



UNIVERSITY of VIRGINIA

OFFICE OF THE VICE PRESIDENT
FOR RESEARCH AND GRADUATE STUDIES

April 21, 2006

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

Dear Mr. Hammond:

We enclose the meeting minutes from our Institutional Biosafety Committee as requested. The documents are complete and unmodified with the exception of specific redactions made for minutes of IBC meetings that occurred between May 2003 and September 2003. The deleted text contains information regarding a Human Investigation protocol that we were asked to review by a sponsor. The terms of this review included a confidentiality agreement which prohibits disclosure of information related to the proposed study. Ultimately, the IBC did not approve the protocol; however, we remain bound by the terms of the confidentiality agreement.

We have not yet implemented any specific policies or reviews in response to the Fink report. We are awaiting guidance from the National Scientific Advisory Board on Biosecurity panel. However, as part of our protocol review process the safety of the laboratory personnel and the public is always our primary concern.

Sincerely,

David Hudson
Associate Vice President for Research
And Graduate Studies

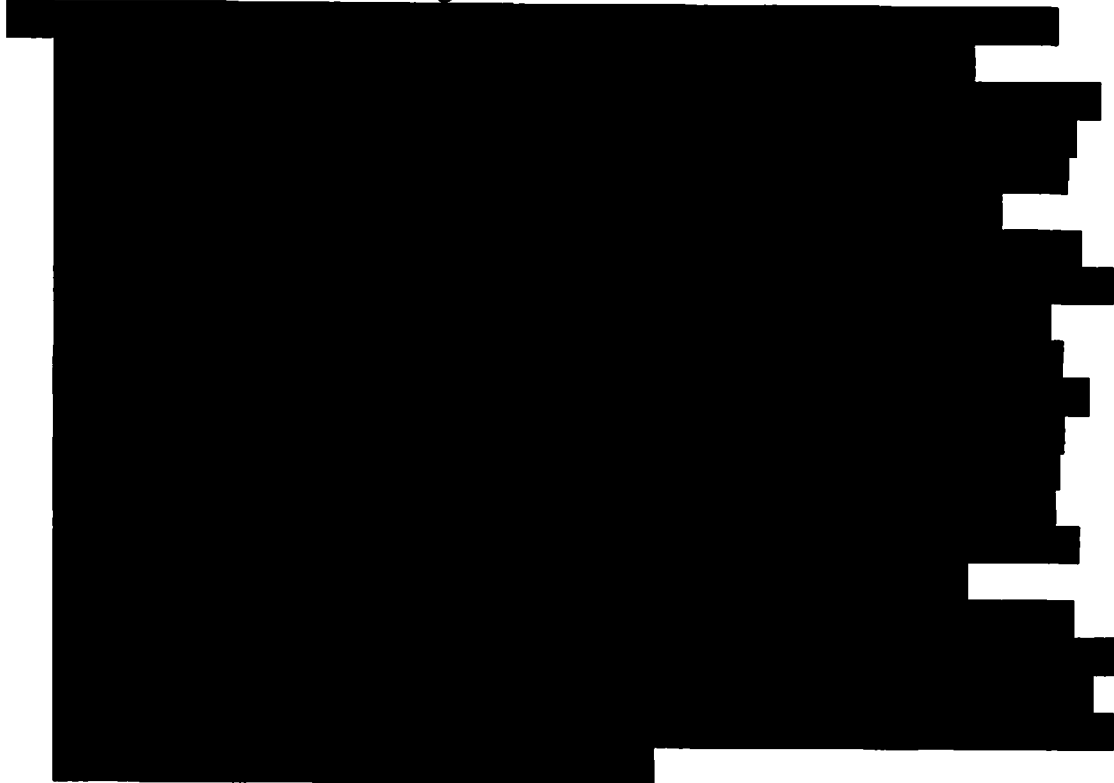
UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

May 12, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Barbara Mann, Peter Ernst, Sanford Feldman, Susan Kiley, and Marjorie Maxey.

1) OLD BUSINESS

- A. The minutes from April 14, 2003 were approved unanimously with corrections. Also, the committee decided Gloria Bowers should email the minutes to the committee for approval right after the meeting. This is to enable us to approve the minutes outside of the meeting.



- C. Dr. Hammarskjöld told the committee that she has finally spoken to someone from OBA about our FACs Core. He was familiar with the brand of FACs machine we are using and the problem with the aerosols. He said that he felt that BSL2 was sufficient for human tissue unless it's known to be more infectious. He also said that testing is not always meaningful so at least universal precautions or BSL2 should be used. If there are larger samples or samples similar to HIV, then you should work with them as BSL2+ (BSL 3 procedures in a BSL2 room). He didn't think that there needed to be changes to the air pressure. Furthermore he said that this machine produces large droplets and that they should fall from the air faster. The operator should let the air clear before continuing with the procedure.

- D. The Texas Tech University case involving Dr. Thomas Butler and the plague samples is continuing. The Wall Street Journal had a substantive article outlining the case. Dr. Butler is still not permitted to leave the county where he lives or to speak to anyone related to his case. It does not appear that many scientific organizations are coming out with any opinions on the case.

3) NEW PROTOCOLS AND RENEWALS:

- A. DR. JAMES REIBEL has never had a protocol. He needs to be approved for a special class he's doing on June 6. We need to see what kind of lab manual he's giving out to the attendees and to see where he'll be doing the work. We should look at the lab before the class.
- B. DR. M. MITCHELL SMITH needs a lab visit.
- C. DR. JESUS RIVERA-NIEVES needs a lab visit. There was some discussion about schistosoma.
- D. DR. JERRY NADLER (136-02) was last visited 12/12/01. He was approved without a lab visit. He did not appear to have any substantive changes.
- E. DR. BARBARA MANN has given us her BSL3 protocol and the lab manual is available to review before her lab visit. She told the committee that the work on her lab is completed. She wants to start work in her BSL3 under BSL3 protocols using the live vaccine (LVS) strain of *F. tularensis* to gain experience in the procedure. LVS is considered a BSL2 agent. They've been tested for their respirators and are set to start. Several committee members wanted to know if this room would be just temporary since Dr. Skalak has opposed it. Dr. Mann said that Judy Maretta is still looking into trailers. Also, if Dr. Petri's proposal for UVA to become an Infectious Disease Center, she would move into the new facilities when they became available. Several committee people expressed their reservations about the trailers and modular buildings. There is concern about the ability to secure them. This also led to a discussion about the futility of buying the modules and then applying to the IBC who would then feel pressure to approve a facility that was already here. Then, it was decided to do a lab visit for Dr. Mann and Susan Kiley, Peter Ernst and Marie-Louise Hammar skjöld asked to do the visit.

5) PROTOCOLS WITH NEW LAB VISITS:

- A. DR. MARTIN A. SCHWARTZ was visited by Kiley and Hedrick on April 30. He uses adenovirus and retrovirus. Dr. Kiley reported that the lab visit went very well and he was approved. His number will be
- B. DR. ADRIAN GEAR was visited by Kiley and Hedrick on April 30. He uses blood. He didn't have any problems and his visit went well. He was approved and his IBC number will be
- C. DR. DAN THEODORESCU (086-99) was visited by Kiley on May 8. His lab was in good order. He has a very competent lab manager. The committee approved him.

6) The next meeting will be June 2, 2003.

OLD BUSINESS:

2. The next business was the hand out in lieu of a lab manual for the Laser Laryngology Lab, which will be held on June 6. The committee approved the handout and approved Dr. Reibel's protocol without a lab visit. The lab will be

[REDACTED]

in the Medical School Histology Lab.
The meeting was adjourned.

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

June 2, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Barbara Mann, Peter Ernst, Catherine Hedrick, Susan Kiley, and Mark Ross.

Since Dr. Mann had to leave early, Dr. Hammarskjöld changed the order of the agenda. She spoke first about the new Biosafety Manager. She said that there were 4 final candidates including David Easton. One of the candidates had experience with Wister and will receive a Ph.D. from Penn this summer. He had experience running animals as well as a BSL3. His name is Tom Leonard and he will take over the Biosafety Manager job. He's due to start in July.

NEW PROTOCOLS

- A. JOANNE LANNIGAN has a new protocol. She's the person who is handling the new FACs core. We need to set up a lab visit. Since she's concerned about people who may need service shortly, we may need to do a quick meeting or an email approval on her as long as everything appears correct.

CHANGES TO EXISTING PROTOCOLS

- A. MICHAEL WEBER (022-96) last visited 9/7/96. He wants to restart his protocol and needs a new lab visit. He's working with polytrophic retroviruses.
- B. JERRY NADLER (136-01) last visited 12/12/01. He's adding Kevin Aylor to his protocol. Dr. Aylor is going to check a system he's designed and if it works as planned, he'll go on to get his own protocol. He is approved to work under Dr. Nadler.
- C. TIMOTHY L. PRUETT (037-96) last visited 11/20/02. He advised us of his new biosafety cabinet. It was noted.
- D. THOMAS SKALAK (146-02) last visited 1/2/02. He's adding new personnel. He was approved.
- E. CAMERON BASS (144-02) last visited 10/15/02. Jim Bolton who is in this lab called because they are planning to increase their storage area for cadavers. They have several plans and want to speak to someone about what they should consider for safety. Dr. Hammarskjöld said that she would speak to him.

NEXT MEETING DATE

Since the new Biosafety Manager will be coming in July, and due to vacations in the summer, it was decided that the next meeting would be August 4 at 5:00 p.m.

OLD BUSINESS

[illegible]

Dr. Ernst had to leave, so we went on to BARBARA MANN's protocol. She would like to begin working in her BSL3 lab with BSL2 material. She wants to become more familiar with BSL3 practices and be ready for her BSL3 lab when it's complete. Everyone agreed that she could work with BSL2 material under BSL3 methods in the room, which will become her BSL3 lab.

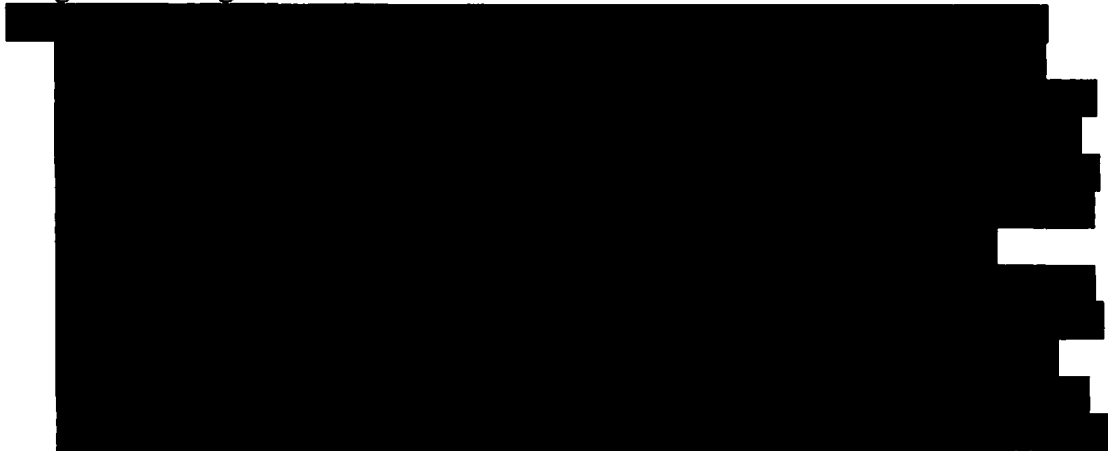
INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

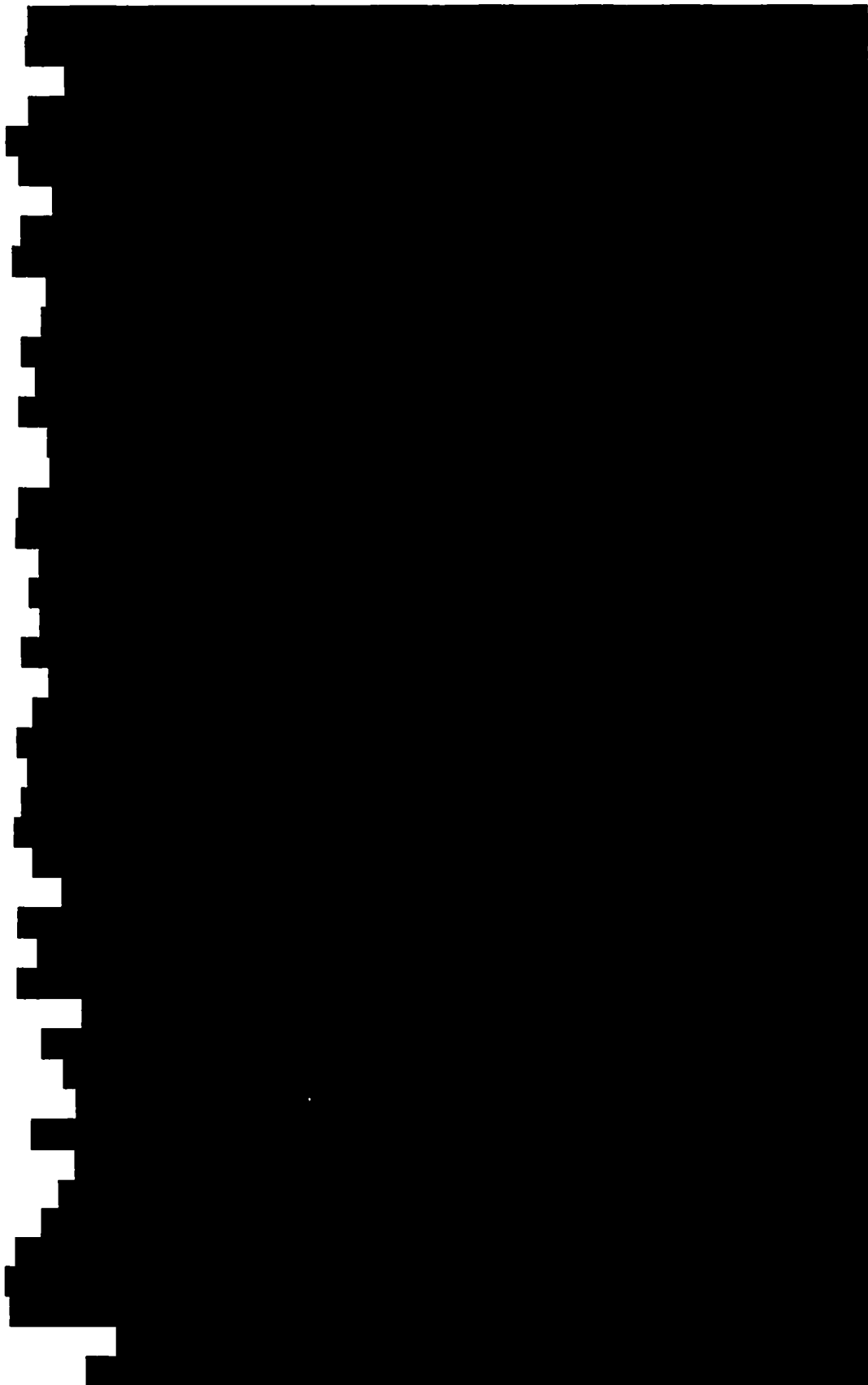
JUNE 10, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Barbara Mann, Peter Ernst, Sanford Feldman, Catherine Hedrick, Susan Kiley, Ronald Turner, Mark Ross and Marjorie Maxey.

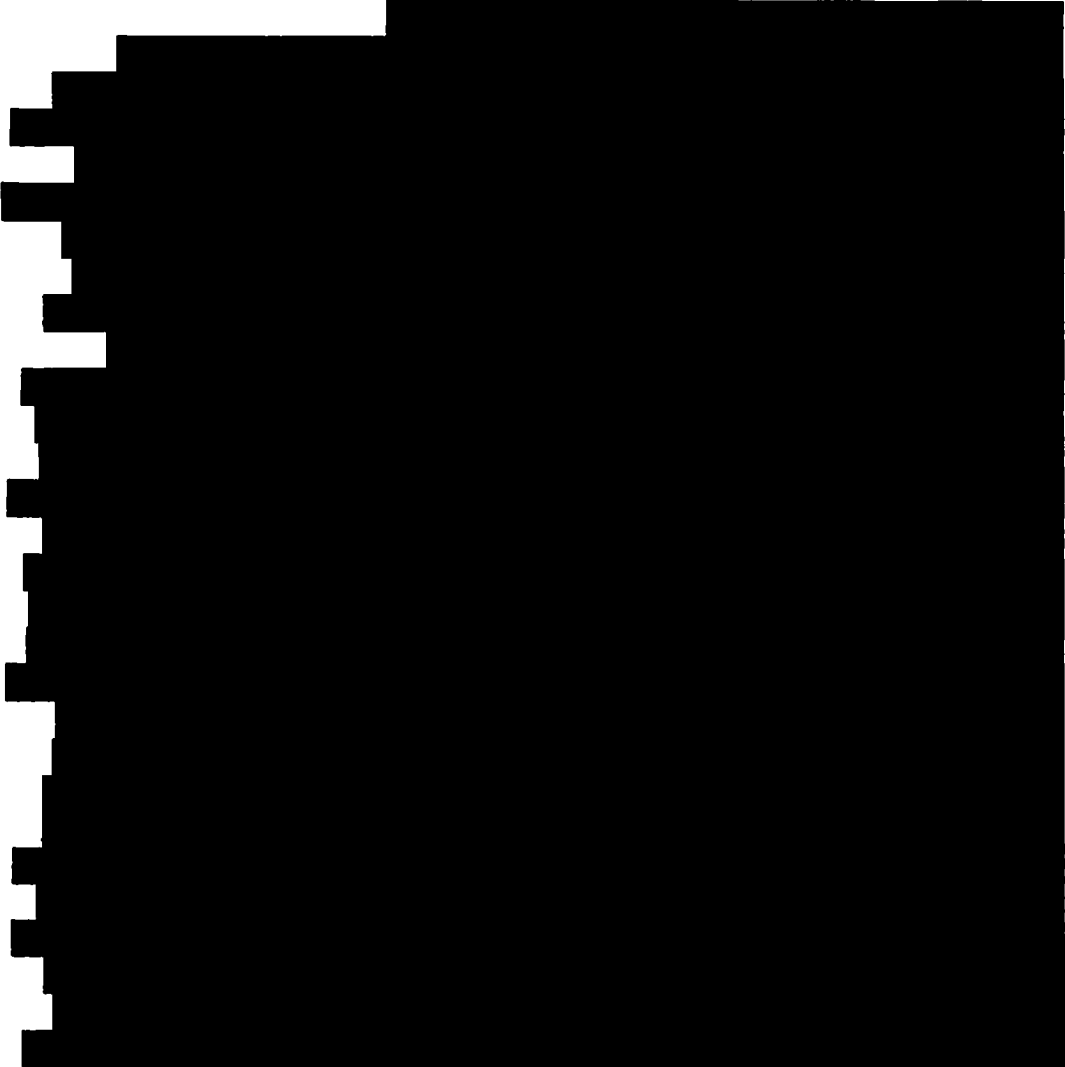
Before Drs. Hedrick and Turner arrived we started the meeting with several short items.

1. J. THOMAS PARSONS (070-98) last visited 4/3/02. He has a personnel change. He wants to add Dr. Julie Turner to his protocol. She will temporarily use Dr. Parson's protocol and facilities until she has her own in space. This was approved unanimously.
2. RONALD P. TAYLOR (049-98) last visited 9/1/00. He would like to use a serum free cell culture of Plasmodium falciparum without any live pathogen with a collaborator, Dr. John Waitumbi, who is spending some time with Dr. Taylor starting June 21. Dr. Mann said that this variety only grows in primates and it is a BSL2 agent. Dr. Hammarskjöld further explained Dr. Taylor's other difficulty of getting a permit for Dr. Waitumbi to bring the material into the country. Under today's culture, Dr. Waitumbi will probably need some documentation when he arrives with the material. Dr. Feldman suggested that he not bring it into the country and just order the material from a supplier here in the states. He thought it would be much easier. The committee approved adding the P. falciparum to Dr. Taylor's protocol with the caveat that he give us documentation that the material was brought into the country legally. (Drs Turner and Hedrick arrived).
3. PETER ERNST (124-01) last visited 9/14/01. He is adding Fransicella holartica to his protocol. It will come from Dr. Mann's laboratory. Dr Ernst left the room. Dr. Mann said that this was a LVS strain and did not cause disease in humans. She also said that we may want to look at this again when her BSL3 lab was up and running since we may not permit material to leave the BSL3 lab. The protocol was approved with the caveat that Dr. Ernst looks for shedding in animals and give shedding data to Dr. Feldman.





The meeting was adjourned.



The UVA IBC had no meeting in July 2003 due to conflicts with members being out of town. It was cancelled.

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

August 18, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Barbara Mann, Peter Ernst, Marjorie Maxey, Sanford Feldman, Susan Kiley, Mark Ross and our new Biosafety Manager, Tom Leonard.

Dr. Hammarskjöld introduced Dr. Tom Leonard, the new Biosafety Manager. Dr. Hammarskjöld said that she hoped that they could finally work together to get a mission statement in place. Dr. Ernst suggested that with Dr. Gomez being permanently appointed to be VP for Research and Public Service, he might want to do this himself. Dr. Hammarskjöld said that she'd speak with David Hudson to see how the Office for Research and Public Service would like to have it done.

LETTERS:

1. Dr. Hammarskjöld reminded the committee of the article done by Pru Thorner in "Research News" and explained that the article elicited a letter from Dr. Neil R. Silva at UVa Student Health in which he appeared to be asking for information on biological materials used at the University. Dr. Hammarskjöld suggested that she and Dr. Leonard meet with Dr. Silva to see how they may help him. It's believed that an overview of the materials that are used at UVa may help him. Dr. Ernst expressed concern that we don't give any medical advice as to how to handle accidents with any of the materials and that Dr. Silva should call ID for specifics in managing potential exposure to infections. Dr. Hammarskjöld agreed that they would act as a coordinator and just give him an overview of the agents used at the University. This may give us a source of feedback to the committee on staff training. We should try to schedule this meeting before 9/8/03.
2. This led to a discussion about the databases. Dr. Leonard said that the current database is not in good shape. Various people on the committee advised him that we haven't send out the declaration for this year. It used to go out each May and when they changed the database last year, it went out in July. Due to the changes in Biosafety Manager, it hasn't gone out this year as yet. Dr. Feldman said that part of the problem with this issue is that Vaughn Kowahl doesn't exclusively take care of the databases. His primary job has something to do with chemical and radioisotope waste handling. Dr. Feldman suggested that the IBC write a letter to Ariel Gomez supporting Vaughn Kowahl being exclusively used to maintain the databases. Dr. Rodeheaver from the ACUC has done a similar letter on behalf of the ACUC. Dr. Feldman said he'd get a copy of the letter for Dr. Hammarskjöld to use to draft our letter. Dr. Leonard asked how long people have to reply to this mailing. He was told that there's never been a due date since there's no compliance threat. Everyone agreed that a

mailing deadline would be useful. Right now the only threat is that people don't get animal protocol approval for those studies that require current IBC protocols.

3. Dr. Richard Enelow (139-02) wrote to advise us that Dr. Jonathan Truwit is using his freezers to hold clinical samples until they can be collected and sent out for a clinical trial. Dr. Feldman said that Dr. Enelow has left the university and is now at Yale University. Gloria Bowers should call Dr. Truwit and find out where his samples are currently being stored.

MR6 DISCUSSION

Drs. Leonard, Feldman and Mann attended the meeting about MR6. Dr. Leonard said that Dr. Fred Hayden wants to create a BSL3+ in order to work with SARS. In order to make such an upgrade, there will have to be substantial modifications. The architects made some changes and there are only 10 suites which are all to one side of the building. Dr. Mann said that the University has been selected as a Regional Center for Excellence, but they did not score as well for the building. Dr. Ernst said that the Dean has said that he will build MR6. Dr. Feldman said that there is a deadline as to when the plans need to be made final as to avoid having to modify the architectural drawings to meet the new changes in the building code.

PROTOCOLS WITH PROVISIONAL EMAILED APPROVALS:

1. JESUS RIVERA-NIEVES (158-03) visited 6/13/03 by Mann. Dr. Mann told the committee that Dr. Rivera-Nieves was very experienced and had set up the lab using good safety practices. The committee formally approved this protocol.
2. JOANNE LANNIGAN (159-03) visited 7/7/03 by Kiley and Hedrick. Dr. Kiley explained that the new cover for the FACs machine and various information Dr. Hammarskjöld received from NIH for Dr. Lannigan, assured her of the safety of the process. Her protocol was formally approved.
3. GERALD R. HANKINS ((067-98) last visited 3/7/01. He's added to his original protocol. He was formally approved.
4. G. PAUL MATHERNE (083-99) visited 7/23/03 by Kiley and Hedrick. Dr. Kiley reviewed his lab visit. He had corrected the incorrect signs on the garbage and had the signage page re-done. These were the only problems. He was formally approved.

PROTOCOLS WITH RECENT LAB VISITS:

1. KENNETH BRAYMAN (157-03) visited 6/6/03 by Mann and Hedrick. Everything was in order. Dr. Mann suggested that Dr. Feldman have lab manuals kept in the BSL2 animal rooms in the Fontaine building. This protocol was approved.
2. MICHAEL WEBER (022-96) last visited 6/6/03 by Kiley and Feldman. He didn't have any lab manual or transport box. He hasn't contacted us to tell us

that this was done. His protocol was approved pending a time in which these items have been done and someone has checked them.

PROTOCOLS WITH CHANGES:

1. LARISSA GUBAREVA (072-98) last visited 9/27/01. Dr. Gubareva included a proposal for using a piece of SARS, which she wants to insert into the attenuated influenza that she uses. It was suggested that she might try the method with a less controversial and unknown virus. Dr. Leonard said that the CDC is allowing some work with SARS at BSL2 level in a diagnostic lab. Dr. Hammarskjöld said that since the work is recombinant, we should ask the OBA how the SARS should be used. Her BSL2 work with influenza A and B was approved.
- ✓ 2. BARBARA MANN (002-96) last visited for BSL2 and May 2003 for BSL3. Dr. Mann left the room while we discussed her protocol. She wants to add *Giardia intestinalis* to her protocol. It was approved. She also asked that she be permitted to add *Francisella tularensis* to the protocol, but she will not use it until her space is approved. She needs to have the material approved for her grant. The committee agreed to add *Francisella tularensis* to her protocol, but she cannot use it until her space is approved.
3. RICH HOROWITZ (100-00) last visited 1/11/00. He needs a lab visit.
4. CHARALES FLICKINGER (038-98) last visited 3/31/03. He has added bacteria strains, *Staphylococcus aureus* ATCC33593, *Salmonella choleraesuis* (typhimurium subsp.) ATCC13311, and *Burholderia* (formerly *Pseudomonas aeruginosa*) ATCC 278531. He needs a new lab visit since he's adding new material. Dr. Leonard asked about OSHA training and why we can't have biosafety training combined with the blood born pathogen training. Various committee members told him that the hospital appeared to want the training to remain as it is. He said that since many of the researchers who need this training did not work in the hospital, that perhaps he could contact them and have the researchers excluded and do their training through OEHS. He said he would look into this.

RENEWALS WITHOUT CHANGES:

1. THOMAS STURGILL (053-98) last visited 11/6/00. Since he hasn't had a lab visit for 3 years, he needs a lab visit.
2. GREGORY A. HELM (7/18/01) last visited 7/18/01. His protocol was approved.
3. LAUREL RICE (058-98) last visited 12/12/01. His protocol was approved.

NEW PROTOCOLS:

1. JEFFREY S. YOUNG needs a lab visit.
2. ANDREI KHOKHLATCHEV needs a lab visit.
3. SUSANNE MOENTER wants to use pseudo rabies and the committee decided that a protocol was not needed.

NEXT MEETING DATE:

The next meeting date will be Monday, September 8, 2003.

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

September 8, 2003

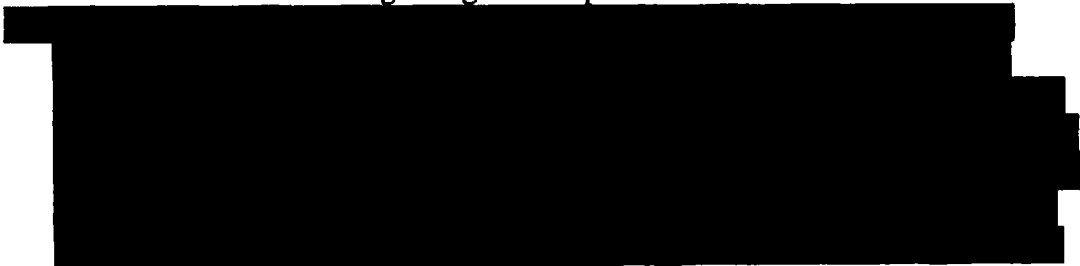
Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Catherine Hedrick, Tom Leonard, Marjorie Maxey, Sanford Feldman, Susan Kiley, and Barbara Mann.


OLD BUSINESS

- A. DR. RONALD TURNER has submitted his resignation. Dr. Hammarskjöld asked everyone to give her suggestions to give to David Hudson or Ariel Gomez on a replacement. Dr. Kiley suggested that we replace him with another clinician. Dr. Hammarskjöld also said that she'd like to start working on a mission statement with Dr. Leonard. She also asked about the declaration and the database. Dr. Leonard said that he had some changes he'd like to make. There were several suggestions of changes that could be made to the declaration, but everyone decided that this year it would be prudent to get the declaration out and use the next 6 months to review it and make pertinent changes. Dr. Feldman wanted to tell everyone about the vivarium space in Jordan Hall that could be used as BSL3. Drs. Hammarskjöld and Leonard will try to view the space. Several people asked about the rains we had last month that caused flooding. Dr. Feldman said that the area where the proposed BSL3 vivarium is located was under quite a bit of water. New ground water tests will be done since the recent tests were during the end of a 5-year drought. David Easton conducted a ventilation test of MR5 BSL3 labs and there are some problems with it. If the exhaust fan fails, there's a 20 second delay in which there is a positive airflow. There are some measures that can be used to counter this problem. After turning off the biosafety cabinet, you can wait 20 seconds in the room before opening the door. This would lessen the effect of the delay. Dr. Leonard wants to see if the problem can be resolved. Dr. Feldman wanted to be sure that Richard Allen had this information. Dr. Leonard reported that Allen was copied on Easton's report and that in the future, David Easton would be handling the Industrial Hygienist portion of the Biosafety Program.
- B. Drs. Hammarskjöld and Leonard met with Dr. Silva and Sandra Murray who is in charge of nursing in Student Health. Dr. Silva and Ms. Murray expressed concern about characterizing student exposures in cases where biological agents are involved. Dr. Hammarskjöld and Leonard identified a number of resources that would help clarify biological exposures, including OEHS, IBC, attending veterinarians and several of the web-based sources. They discussed the problem with allergens and animal use. Dr. Silva thought that certain people who may be susceptible to animal bites may benefit if an epi-pen were available to them. He also said that it would be problematical to those persons who had medical problems with the pens and that until this medical issue was medically assessed, the epi-pen could not go further. It appeared to Drs. Hammarskjöld and Leonard

that most of Dr. Silva's concerns were about allergens and animal handling. Dr. Feldman said that we have a mycobacterium problem in Gilmer Hall with the frogs. The facility is demonstrating high levels of mycobacterium marinum contamination. There may be a lesser problem hidden in this with Mycobacterium ulcerans. During a molecular microbiological evaluation of the frog facility, it appears that almost everything is contaminated with Mycobacterium marinum. Dr. Feldman will be amending his IBC protocol so that he can buy some M. ulcerans to design a PCR test for this material to help in controlling this problem. This is complicated by the fact that in trying to treat it before reporting it to Dr. Feldman, the users gave the frogs antibiotics (isoniazid and kanamycin) which slowed the mycobacterium for awhile, but now the strain in the aquariums is antibiotic resistant. The magnitude of environmental burden is unknown. Mycobacterium ulcerans outbreaks in Xenopus tropicalis has been reported by other institutions and an isolate from UVa was typed as M. ulcerans. It causes severe ulcers in humans. Dr. Hammarskjöld stated that this is not really an IBC problem, but it is a Biosafety problem. She explained that the Mycobacterium was not part of a protocol, and so was not research material. The IBC may want to ask that the rooms where the frogs are be posted as BSL2 since the contamination appears to be so severe. So far there haven't been any M. ulcerans infections in any workers. It was suggested that we might want to contact Occupational Health. Dr. Feldman also wanted to tell the committee about Dr. Kedes whose lab tech inoculated her finger with Kaposi sarcoma virus (KHSV) while inoculating mice. They have been inoculating mice with human tissue and KHSV, but had failed to alert the animal personnel or to post the room or the cages ABSL-2. Dr. Feldman met with Dean Kedes, Chris Parson and the tech to explain the procedures. He also suggested that the tech go to Occupational Health. Part of the problem stems from the PI not having entered the animal facility. Dr. Hammarskjöld didn't think he was approved for ABSL2 animal work. It led to discussions of where the posting should appear, the outer or inner rooms. Dr. Hammarskjöld stated that both the inner and the outer doors need to be posted. Dr. Ernst suggested that sometimes language problems occur in which people don't really understand the directions, but nod that they do understand. Dr. Leonard said that he's been speaking to Barry Farr and that he's agreed to allow him to do Biosafety Training for the university and Dr. Farr would retain the training of the clinical staff.

- C. DR. JONATHAN TRUWIT who had been storing samples of blood and serum in Dr. Richard Enelow's freezer is now storing them in Dr. George Verghese's lab. He will have Dr. Verghese give us a protocol.



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- E. DR. PETER ERNST (124-01) visited 9/14/01. He added Francisella to his protocol, which was approved last June with the caveat that he does some experiments for Dr. Feldman regarding transmission to mice. Currently there is an area appropriate for this study and although the strain of Francisella is not harmful to people, it is extremely harmful to mice. Dr. Ernst's former protocol was approved and it was approved that he can use Francisella for the animal study on shedding that Dr. Feldman had requested. It's understood that the limits on this material is not due to harm to people, but rather problems that could occur to the mouse population.
- F. DR. KEVIN HAZEN (017-97) has asked that he be permitted to use BSL2 materials in his BSL3 lab until such time as the BSL3 lab has been approved. It was decided that we could do a joint lab visit for Drs. Turner and Hazen.

RENEWAL PROTOCOLS:

- A. DR. THOMAS BRACIALE (018-99) last visited 10/3/02 has no changes except personnel to his protocol. He was approved.
- B. DR. COLEEN MCNAMARA (031-97) last visited 4/23/02. She was approved.

PROTOCOLS WITH LAB VISITS:

- A. DRS. RUTH STORNETA and PATRICE GUYENET (012-99) visited 8/20/03 by Kiley and Mann. Dr. Kiley said that the lab was in great shape and they even had an animal experiment set up so that the IBC could view what they actually do. Their protocol was approved.
- B. DR. P. TODD STUKENBERG visited 8/26/03 by Kiley and Leonard. Dr. Kiley reported that the lab was in good shape. They still need to get a transport box, but she was confident they would get it. They were approved and given the number 160-03.
- C. DR. ERIK L. HEWLETT (021-00) visited 9/3/03 by Leonard and Hammarskjöld. Dr. Hammarskjöld said that the visit went very well. They were in generally good shape and had some questions about when to use their signs. They also may get a push code lock for their BSL2 rooms. They were approved.
- D. DR. RICK HOROWITZ (100-00) visited 9/3/03 by Leonard and Hammarskjöld. Dr. Hammarskjöld said that they used murine ecotropic virus, but they didn't appear to understand the difference between ecotropic and amphotropic. Although ecotropic is not BSL2, she suggests that we treat it as such since many people do not understand the difference and may start using ecotropic and later get amphotropic, but not take proper precautions. Everyone

agreed with this and the committee approved this protocol. Dr. Hammarskjöld went out of the room while we discussed the final 3 protocols.

- E. DR. MARGO ROBERTS (090-99) visited 9/8/03 by Kiley, Hedrick and Leonard. Dr. Roberts shares a BSL2 with Drs. Rekosh and Hammarskjöld. The biosafety cabinets need to be recertified and the outer door fixed. This protocol was approved pending proof of the recertification and the fixed door.
- F. DR. DAVID REKOSH (026-96) visited 9/8/03 by Kiley, Hedrick and Leonard. Dr. Rekosh and Hammarskjöld share a BSL2+ facility, which was in good order. They need to have a lab plan for the BSL2+ and the biosafety cabinets recertified. This protocol was approved pending the biosafety cabinets recertified in BSL2 and BSL2+, the lab plan for BSL2+ and the door fixed in BSL2.
- G. DR. MARIE-LOUISE HAMMARKSJÖLD (025-96) visited by Kiley, Hedrick and Leonard. Dr. Rekosh and Hammarskjöld share a BSL2+ facility, which was in good order. They need to have a lab plan for the BSL2+ and the biosafety cabinets recertified. This protocol was approved pending the biosafety cabinets recertified in BSL2 and BSL2+, the lab plan for BSL2+ and the door fixed in BSL2.

NEW PROTOCOLS:

- A. DR. GERALD L. BROWN is a psychologist doing an experiment with saliva. He'll need a lab visit.
- B. DR. ADAM GOLDFARB (104-00) last visited 1/19/00 needs a lab visit since he hasn't had one for 3 years and because he's adding human tissue to his protocol.
- C. DR. JULIE TURNER wants to do BSL2 work in Kevin Hazen's BSL3 space until it becomes BSL3. She had previously asked for BSL3 approval, which is on hold due to the physical problems in MR5.

NEXT MEETING DATE:

The next meeting date will be Monday, October 6, 2003.

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

October 6, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Tom Leonard, Marjorie Maxey, Susan Kiley, and Barbara Mann.

Old Business:

Dr. Hammarskjöld opened the meeting by speaking about the MR6 plans. The "Daily Progress" had a story indicating that NIH had not funded the MR6 building and that the Board of Visitors would be voting on building MR6 shortly. Dr. Mann confirmed this and said that the timetable for construction isn't known right now. She reminded everyone that during the submission of the grant to NIH, it had been said that if NIH didn't support the construction, the building would likely still be built, but may take longer to build.

Dr. Leonard then told the committee that the USDA was coming tomorrow to inspect the BSL3 in MR5 and that on 10/29/03, the CDC would have a team of inspectors here to look at the BSL3. Dr. Kiley asked if the air handling problems had been fixed and if those problems had been corrected in MR6. Dr. Leonard said that they still needed to do a surrogate aerosol test on the BSL3 rooms, but that proper changes had been made in the MR6 plans. Dr. Hammarskjöld asked when the IBC could expect to do a final inspection on these BSL3 rooms and was Kevin Hazen still planning on using his room. Dr. Mann said that the last she had heard Kevin Hazen was still using his BSL3 room. She wants the IBC to give her approval after the CDC approves her space. She'll request the material after CDC and IBC approval. Right now there is only one person permitted to ship *F. tularensis*. The receipt of the material will be through Environmental Health to Dr. Leonard. Right now none of the FBI approvals have been received except for David Easton. These approvals need to be in place before we get the *F. tularensis*.

Changes to existing protocols:

- A. DR. TOM G. OBRIG (079-99) added Donald Hunt's lab personnel to his protocol. This was approved, but Dr. Obrig needs to have the new people do a training course with Tom Leonard. No lab visit was necessary.
- B. DR. FREDERICK HAYDEN (053-98) He wants to continue a study they started in May 19-24, 2003 with an additional hotel study on November 25-30, 2003. This is part a longstanding practice that the University has supported in which people are solicited to receive a rhinovirus inoculation and are housed in a local hotel. Although everyone believes that there is little probability of this being a biosafety problem if appropriate procedures are followed, there is some problem with the perception and there may be problems with liability. Dr. Leonard asked if any attorney had looked into this matter. Dr. Hammarskjöld explained that we have had past meetings with Dr. Hayden about this study. Dr. Ernst said that it may be time to reassess this practice. Everyone expressed concern about how this study would appear to the outside. It was agreed that this study would be approved,

but it would be conditional with Dr. Hayden giving us updated information as to whether this practice is still done nationally. He needs to tell us how many of these tests are being done and where. Also, he should tell us if NIH still supports this practice? The committee approved this study with the condition that we will review the question of hotel studies prior to providing approval of future proposals. When we write to approve this hotel study, we should give him a deadline such as the end of the year to get us this information and to meet with Drs. Leonard and Hammar skjöld about this work.

- C. DR. ADAM GOLDFARB (104-00) last visited 3/20/03. His lab manual has always shown that he has human cells in the lab, but he never added it to his protocol. He is adding human cells now. His protocol was approved.
- D. DR. KENNETH BRAYMAN (157-03) wants to add adenovirus to his protocol. He'll be working with Dr. Nadler's personnel. He was approved.
- E. DR. ROBEIN A. FELDER (039-97) was last visited 5/21/01 and is adding personnel. His addition was approved.

Renewals:

- A. DR. JAY BROWN (057-98) was last visited 1/29/01. He's renewing with no changes. He was approved.
- B. DR. ULRIKE LORENZ (092-99) was last visited 9/29/99. She's renewing with no changes. She needs a 3-year lab visit.
- C. DR. JOANNA GOLDBERG (059-98) was last visited 5/13/02. She is renewing with no changes. She was approved.

New Protocols:

- A. DR. GEORGE M. VERGHESE sent his lab manual with his application. He needs to have a lab visit.
- B. DR. BRIAN P. HELMKE needs to have a lab visit.
- C. DR. CATO LAURENSIN needs to have a lab visit.
- D. DR. ARTHUR WELTMAN needs to have a lab visit.
- E. DR. GERALD L. BROWN needs to have a lab visit.

New Business:

It's been suggested that we need to develop a policy on Human Cell Lines. Currently we have been suggesting that everyone use all human cell lines just like primary human tissue, which we treat as BSL2 unless it contains a pathogen that makes it higher. If an investigator has some reason to believe that his cell lines don't need to be treated as BSL2, then he must make a case for it. Dr. Leonard will write up a policy about this to codify what we have been doing.

Joanne Lannigan is uncomfortable working with untested human tissue. Dr. Hammarskjöld said that when she contacted OBA for guidance in this issue, they said that with the instrument that Ms. Lannigan uses, universal precautions would be indicated with untested human tissue. It's too expensive for researchers to test everything. She feels that even with a respirator, she can't get the machine clean enough. A new machine may not give her the comfort level she wants. Tom Leonard said that he did most of his dissertation research using FACs machines and is familiar with safety issues associated with analysis and sorting. Dr. Hammarskjöld will arrange to introduce Tom Leonard to Joanne Lannigan to see if he can assist her.

The next meeting is Monday, November 10, 2003.

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

November 10, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Sanford Feldman, Tom Leonard, Marjorie Maxey, Susan Kiley, Barbara Mann and Mark Ross.

OLD BUSINESS:

Dr. Hammarskjöld asked Dr. Leonard to open the meeting by telling everyone about the United States Department of Agriculture (USDA) and Center for Disease Control (CDC) visits. He reported that the USDA arrived with a 26 page checklist that included a biosecurity plan. This inspector hadn't much experience so she questioned the lack of a shower out of the BSL3, but his sense was that the visit went relatively well. The CDC visit was more rigorous. The CDC inspector was especially concerned that the freezers be locked in the BSL3 although the room itself is secure. Also there should be signs for some of the procedures from the manual so that emergencies can be dealt with immediately. We should be getting a written report with the recommendations and we'll have a better idea then as to how thorough our procedures are. We should get an interim registration number before we can start BSL3 work. We have 6 of the 8 background checks. Ironically, Dr. Mann and Ralph Allen haven't been approved, but they are on their 12th and final step.

Dr. Turner was able to come and discuss hotel studies for Rhinovirus with the committee. He has three different proposals. In two he's using rhinovirus in hotel studies. One is his usual application in which he evaluates Echinacea in a Rhinovirus challenge. The other is the same as one of Dr. Hayden and Gwaltney's protocol in which they evaluate Pleconaril in a rhinovirus challenge. These have been done at UVA and similar challenges in hotel studies are currently being done in Huston, Texas. He also assured the committee that he is still receiving grants to do this through NIH.

The third proposal is part of a Genomic Study to Investigate the Pathogenesis of Rhinovirus colds. This protocol differs from the previous in that after the volunteers are infected, they are not sequestered. He wanted to come to assure the committee that this was a relatively safe protocol. Due to the high viral load in the community, Dr. Turner and his study are not appreciably increasing the possibility of contracting a cold. He had letters from colleagues to attest to this and to explain that they do similar protocols in Wisconsin and Calgary and have not had any problems. In the handouts to the patients, they will be encouraged to wash their hands which is the only easily available method to lessen transmission. He told the committee that infectivity follows symptoms. When a volunteer has the most symptoms, they are the most contagious.

He said that they are able to do these non-hotel studies with rhinovirus, but that it may not be reasonable to do it with influenza since it is a disease of more substance. He said that he could conceivably do it in his Echinacea study, but would like to have it remain that they sequester volunteers since they are doing their final cohort and wouldn't want to change the procedure at this time. He said that sequestering in rhinovirus challenges is not driven by infection control, but by access to the volunteers at specific times. When he

did these challenges in Charleston, he offered to pay anyone as a volunteer if they could show that they had been infected by his rhinovirus and he had no successful challenges. Sometimes there's a preference to have volunteers available.

Dr. Leonard said that he had concerns about bringing a potentially infectious material into a hotel with no containment and concerns that there could be contamination to environmental surfaces. He had more of a perception problem than a safety problem. Dr. Turner said that the hotels are aware of what they have. He rents whole floors and seldom has anyone other than the volunteers on a floor. They are inoculated in a conference room and the conference room is thoroughly stripped and cleaned by the hotel staff after they are there. Dr. Turner said that these studies are often written about in the Daily Progress as well as national media and it has always been in a positive light. Dr. Turner related that he had only once had a patron of one of the hotels threaten to sue the hotel. Dr. Turner wrote a letter to them about the study and never heard from them again. He did not think that this protocol was a realistic liability.

Dr. Turner said that he didn't perceive this as a safety problem, but rather a legal problem. Several other members said that we could only comment on the safety aspect and that we'd have to advise others of any legal problems.

The committee had no more questions and Dr. Turner left. The committee voted to approve each protocol.

DR. JEFFREY WIMSATT withdrew his application to do the work he proposed, but he's asking that we approve him storing human pregnancy tissues in his freezer in B-068 Jordan Hall. He'll reopen his protocol if he is able to use the tissue. He was approved and the committee asked that he appropriately mark the freezers with signs.

NEW BUSINESS:

Dr. Leonard presented the Committee with a draft proposal for IBC policy regarding use of human cell lines. It was from the University of California in San Francisco (see appendix i). Dr. Kiley said that it's a timely proposal since there was an article on this in the ABSA. The committee felt that the word "sufficient" was too vague. Dr. Mann suggested that everything after containment be deleted. Everyone agreed. Also Dr. Ernst brought up the possible problem it will pose in getting work done with the Flow Cytometer. Both Dr. Ernst and Feldman cautioned against passing this today with an immediate effective date since it would be kinder to give everyone warning. This is especially so since there isn't a clear danger in not having this policy. Dr. Feldman said that probably in the animals, only 1/10 of 1% of the protocols would be affected, however there may be an additional financial burden that the PIs would need to know. It was suggested that we'd get more support from the PIs if we educate them rather than just pass this for immediate implementation. It was suggested that this policy be phased in over the next year. We should tell the faculty that regulations are changing everywhere and that the University will be changing too. We should announce these changes now, but implement them when we do the next declaration. Dr. Leonard will do the emails.

NEW PROTOCOLS and PROTOCOLS WITH CHANGES:

- A. DR. FREDERICK HAYDEN (053-98) last visited 09/27/01). He sent another hotel study at the same time we sent our letter. The committee approved the

hotel study regarding rhinovirus and the continuing of his laboratory work. However, the committee asked Dr. Leonard to contact Dr. Hayden about his hotel studies with influenza. He can use Dr. Turner's risk assessment as an example of what the committee would like to have Dr. Hayden give us regarding the influenza studies in hotels.

- B. DR. ERIK L. HEWLETT (021-00) last visited 09/03/03. He's adding B. anthracis (Sterne strain). Although the Sterne strain is an exempt strain, the committee is unclear as to what is being returned. The committee wants to be sure that they will not make a non-exempt from an exempt. Also, if their not using a lethal strain, why do they want to get vaccinated? Dr. Leonard will contact Dr. Hewlett to get clarification.
- C. DR. RICK HOROWITZ (100-00) last visited 9/4/03 wants to add recombinant adenovirus to his protocol. Currently has murine leukemia retrovirus. Since he was so recently visited and his visit was exceptional, the committee agreed to add this material to his protocol without a lab visit.
- D. DR. OTHMAN GHRIBI. This material is a toxin and does not need BSL3. Dr. Leonard will talk to Dr. Ghribi about how he needs to set up his lab for this work. Also, he may need to keep an inventory of how much Ricin he has so as not to come under the Select Agent Regulations. Dr. Leonard said there are forms for tracking from the distributor called EA101. Dr. Leonard said that he would help Dr. Ghribi.
- E. DR. SUN-SANG J. SUNG needs to fix his form for lab animals. He also needs to have a lab visit.

NEW PROTOCOLS WITH LAB VISITS:

- A. DR. FABIO COMINELLI visited by Ernst, Feldman and Hedrick on 10/28/03. Dr. Feldman said that Dr. Cominelli's lab was in good order. He had to purchase a transport box, which Gloria Bowers reported that he had done. His protocol was approved.
- B. DR. THERESA PIZARRO visited by Ernst, Feldman and Hedrick on 10/28/03. Dr. Feldman recommended her protocol be approved. Her protocol was approved.
- C. DR. HELMKE visited by Leonard on 10/17/03. Dr. Leonard said that Dr. Helmke's lab only needed some stickers for the freezers. He was approved.
- D. DR. CATO LAURENCIN visited 10/30/03 by Barbara Mann. Dr. Mann told the committee that everything was correct in Dr. Laurencin's lab and he was approved.
- E. DR. GEORGE VERGHESE visited 10/30/03 by Barbara Mann. He is only storing cells. He was approved.

RENEWALS WITH CURRENT LAB VISITS AND NO CHANGES:

The following protocols were approved for renewal since they have current lab visits and no changes:

- A. DR. MARWAN K. AL-SHAWI (071-98) last visited 10/10/01.
- B. DR. CAMERON BASS (144-02) last visited 10/15/02.
- C. DR. DOUGLAS BAYLISS (087-99) last visited 11/20/02.

- D. DR. BRETT BLACKMAN (147-03) last visited 12/02/02.
- E. DR. THOMAS BRACIALE (018-99) last visited 10/3/02.
- F. DR. TIMOTHY BULLOCK (145-02) last visited 10/28/02.
- G. DR. JOHN DAVID CASTLE (143-02) last visited 09/25/03.
- H. DR. JEFFREY T. CORWIN (138-03) last visited 06/04/02.
- I. DR. SHU MAN FU 9085-99) last visited 01/29/03.
- J. DR. RICHARD L. GUERRANT (009-96) last visited 12/6/02.
- K. DR. STEVEN L. GONIAS (003-96) last visited 5/22/02.
- L. DR. KEVIN C. HAZEN (017-96) last visited 11/25/02.
- M. DR. J. OWEN HENDLEY (033-98) last visited 01/20/03.
- N. DR. PETER W. HEYMAN (128-01) last visited 09/10/01.
- O. DR. YOUNG S. HAHN (077-99) last visited 12/19/02.
- P. KEVIN T. HOGAN (137-02) last visited 04/02/02.
- N. DR. ADAM KATZ (140-02) last visited 09/04/02.
- Q. DR. KLAUS LEY (042-97) last visited 04/16/02.
- R. DR. RONG LI (139-02) last visited 05/13/03.
- S. DR. MANI S. MAHADEVAN (141-02) last visited 09/25/02.
- T. DR. RAGHAVENDRA MIRMIRA(131-02) last visited 08/30/02.
- U. DR. CHRISTOPHER A. MOSKALUK (078-99) last visited 03/21/03.
- V. DR. K. KEVIN PFISTER (120-01) last visited 03/29/01.
- W. DR. TIMOTHY L. PRUETT (037-00) last visited 11/20/02.
- X. DR. GEORGE RODEHEAVER (020-20) last visited 09/10/02.
- Y. DR. LAUREL RICE (058-98) last visited 12/12/01.
- Z. DR. MARTIN SCHWARTZ (150-03) last visited 04/30/03.
- AA. DR. MARGARET A. SHUPNIK (060-98) last visited 05/13/02.
- BB. DRS. RUTH STORNETTA/PATRICE GUYENET (012-99) last visited 8/20/03.
- CC. DR. MICHAEL O. THORNER (056-98) last visited 08/30/02.
- DD. DR. JULIUS ZHU (135-02) last visited 02/22/02.

RENEWALS WITH CURRENT LAB VISITS AND CHANGES:

- A. DR. AMY BOUTON (074-99) last visited 07/24/02). She's adding a new material. She was approved without a lab visit.
- B. DR. THOMAS E. BROWN (122-01) last visited 12/05/02. He has added a room in Cobb Hall. He needs to be visited.
- C. DR. WA'EL EL-RIFAL (155-03) last visited 03/03/03. He has changes in the spaces he's using for BSL2.
- D. DR. VICTOR H. ENGELHARD (016-98) last visited 11/25/02. He's adding recombinant retroviruses. He was approved without a lab visit.
- E. DR. SARAH J. PARSONS (007-98) last visited 11/07/02. She has deleted Sindbis and Vaccinia from her protocol. She was approved without a lab visit.
- F. DR. LAUREL RICE (058-98) last visited 12/12/01. She has removed recombinant DNA from her protocol, but she has it in her description. Emailed to clarify.

RENEWALS WITH EXPIRED LAB VISITS:

The following protocols need to have lab visits:

- A. DR. LARRY BORISH (115-00) last visited 11/16/00.
- B. DR. FELICIA GASKIN (097-99) last visited 10/11/99.
- C. DR. DEAN KEDES (082-99) last visited 10/19/00.
- D. DR. PETER LOBO (023-97) last visited 8/25/00.
- E. DR. LISA PALMER (107-00) last visited 3/20/00.
- F. DR. RICHARD D. PEARSON (014-00) last visited 1/19/00.
- G. DR. STEVEN POWELL (040-98) last visited 07/21/00.
- H. DR. JAMES R. ROCHE (111-00) last visited 6/16/00.
- I. DR. MARK STOLER (061-98) last visited 5/19/98. He uses fixed human papillomavirus cells and will contact us before he uses unfixed cells. We haven't visited him since he's still using the fixed cells, but he sends us a registration document each. Dr. Feldman suggested that Ms. Bowers call Dr. Stoler and inquire as to where he gets his papillomavirus. Dr. Stoler supplies several people with this material. He needs to have a lab visit.
- J. DR. RONALD TAYLOR (049-98) last visited 9/1/00.
- K. DR. WILLIAM F. WALKER never got his lab visit because he moved.

The committee agreed that the next IBC meeting will be Monday, December 1 at 5:00 p.m.

Appendix i

Draft proposal for IBC policy regarding use of human cell lines 10 November 2003

All cell and organ cultures of human origin, including well-established cell lines, shall be handled in accordance with the OSHA Bloodborne Pathogen Standard and under Biosafety Level 2 (BSL2) containment unless the PI can demonstrate, to the satisfaction of the Biosafety Committee, that a cell culture has been sufficiently screened and shown to be free of bloodborne pathogens.

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

December 1, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Tom Leonard, Susan Kiley, Barbara Mann and Mark Ross.

OLD BUSINESS:

A. The Committee reviewed the declaration and registration mechanics. Dr. Leonard found the declaration and registration unwieldly. The Animal Care and Use Committee (ACUC) needs an approval number and a current letter which describes the materials they are approved to use. Dr. Leonard wanted to know why we had both the declaration and the registration. He asked if a PI did not have a current declaration, but had a current registration, was the PI in good standing? And if he declared, but did not give a current registration, was the PI in good standing? Dr. Hammarskjöld told him that the letters approving work were good for one year or until the committee is notified of a change. Although we have been asking PIs to keep their declaration current, we have not been penalizing them for failure to keep it current. Dr. Leonard thought that perhaps we could combine the declaration and registration process into a single online procedure. That way PIs only need to do it once and the IBC could track the registration online. He's going to check with Vaughn Kowahl about an online format and expects that Vaughn will be able to present a prototype online system by April.

B. The Committee then looked at the draft policy on Human Cell Use. Dr. Mann asked how we would publicize it. Dr. Leonard thought that an announcement via email would be one way to announce the policy. Everyone approved of the policy, but the committee wants to hold off on the enforcement of this July 1, although the policy is recommended immediately. That way it can be incorporated into the new declaration.

C. Dr. Leonard advised the committee that the University now has a Certification of Registration from the CDC and we are approved to conduct work with the select agents we have asked to work with. There are some items still to be addressed in the report from the CDC, but nothing that is impossible. The items are things such as locking the freezers and incubators in the BSL3. We have still not received our U.S. Department of Agriculture (USDA) approval or their suggestions for improving the lab. It is unclear as to whether we can continue without the USDA approval. The background checks have all been completed. Both BSL3 labs are due to be certified. There is still talk of taking them back. Dr. Feldman is trying to get a grant to convert the BSL3 animal space to lab space since the air handling is changing in Jordan Hall with the new renovations. The plan is to ultimately move Barbara Mann to Jordan Hall. There have been meetings about MR6 and the vivarium has been removed. The BSL3 labs have been changed and are no longer at the top of the building, but have been moved to the basement. Tom Leonard said he wasn't at the meeting in which this change

was made. Dr. Hammar skjöld expressed concern that these types of changes are being made to buildings without consulting the IBC since they will be asked to approved these spaces. Dr. Mann said that she'd ask Dr. William Petri to arrange to send minutes of the building meetings to Dr. Hammar skjöld. Everyone expressed agreement that they want to avoid the problems of MR5.

D. Dr. Leonard then gave an update on other committee matters. Dr. Leonard heard from Gloria Hipskind who works with Dr. Hayden. She advised him that Dr. Hayden will no longer be doing influenza hotel studies, but instead will do hotel studies on rhinovirus. Since Ron Turner gave the committee such a good background on using hotel studies for rhinovirus, we won't need a similar background from Dr. Hayden.

Dr. Leonard has not heard from Erik Hewlett on anthrax.

Dr. Hammar skjöld said that she has more time than usual this month and can now set up an appointment with Ariel Gomez and David Hudson to meet and discuss the University's IBC policy with Tom Leonard.

E. OTHMAN GHRIBI responded to Dr. Leonard's request about his use of ricin. He will not exceed 10 mg so he won't be under the Select Agent protocol. He said that he thought the webpage advised him to use BSL3, but he's seeking advice on containment and use of the material. Dr. Leonard said that it should be used with a chemical protocol. We should set up a lab visit.

CHANGES TO PROTOCOLS:

- A. TODD STUKENBERG (160-03) last visited 8/26/03. He would like to add lentivirus-based vectors to his protocol. Dr. Hammar skjöld said that lentivirus usually means HIV. It should be possible to use as BSL2 since there is no envelope and he will use VSVG. If he uses BSL2, he should do so strictly. Dr. Hammar skjöld wants to attend the visit.
- B. JUDITH WHITE (080-99) last visited 11/20/02. She wants to add the use of Ebola GP cDNA with VSV pseudotype particles. Amy Bouton was just approved for this. Dr. White has a lot of experience with viruses and has been working with the Ebola GP cDNA. Her protocol was approved without a lab visit.
- C. KLAUS F. LEY (042-97) last visited 4/16/02. He wants to add room 1238 in MR5 to his protocol. Since it's a new space, we will do a lab visit.

RENEWALS WITH NO CHANGES:

- A. CATHERINE HEDRICK (099-99) last visited 3/15/02 was approved with no changes.
- B. J. THOMAS PARSONS (070-98) last visited 4/3/03 was approved with no changes.

NEW PROTOCOLS:

- A. JOHN BARCIA needs a lab visit.

- B. LLOYD S. GRAY needs a lab visit.
- C. GERALD BROWN is doing research on salivary cortisol, dehydroepiandrosterone and testosterone interrelationships in controlled healthy young males. He only needs to store samples of saliva until they can be mailed. He has sent us letters to verify that the refrigerators where the saliva is stored have signs and that the people in the labs know what is there. He has a small lab manual and they have done their universal precautions. They were approved without a lab visit.

The next IBC meeting will be January 5, 2004.

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

January 8, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Sanford Feldman, Tom Leonard, Susan Kiley, Barbara Mann and Mark Ross.

Dr. Leonard announced that his new Associate Biosafety Officer, Jean Gatz would start work on February 2. She will assist him and he hopes that she can assist the members of the committee by doing the more standard lab visits. Committee members would still go to new lab visits and to those people the committee believes may need help. He also told the committee that there will be multiple contractors available for the Biosafety Cabinets and that ultimately, he hopes to have the inspections be "in house".

Dr. Mann said she needs to have her BSL3 inspected. She has received all of her approvals from the CDC and the Department of Agriculture.

Dr. Hammarskjöld asked about MR6. She wanted to know if it was possible to separate the airborne from the non-airborne pathogens since it's unknown as to what will be needed in the future. It is easier to work with non-airborne pathogens. She also asked how long it would be before there couldn't be any changes. Also, there should be some security for any Select Agents. There is a Vivarium meeting Tuesday, 1/15/04 for MR6.

OTHER BUSINESS:

1. The group discussed the meeting times. Several people have conflicts with Monday, Tuesday, and Wednesday. Thursday would be a more convenient time if we can start earlier. It was agreed that we would change the meeting time to the first Thursday of the month at 4:30 p.m.
2. Dr. Hammarskjöld announced that Dr. Hedrick resigned from the IBC. We now have 2 vacancies. She and Dr. Leonard will try to meet with David Hudson and/or Ariel Gomez to discuss getting replacements. Dr. Sanford suggested that we ask Gerri Hankins.
3. Dr. Sanford told the committee about Kevin Lee and several others who are receiving human adipose tissue for stem cell isolation for use in animals without getting IBC approval. He believes that they're from the Adam Katz lab. Ms. Bowers could only find Adam Katz and Roy Ogle who are using fat cells. Their labs claimed that they don't give out their cells. The committee asked that Ms. Bowers determine who is giving out the cells and speak to them about only giving cells to people who are approved to use them in their labs.
4. DR. FREDERICK HAYDEN (053-98) is approved for the smallpox vaccine study. The committee then approved him for the hotel study using rhinovirus, which duplicates a previous study.
5. DR. PETER ERNST (124-01) wants to add *Campylobacter jejuni* as a foil to contrast responses with *H. pylori*. After he left the room, his protocol was approved without a lab visit.

6. Dr. Leonard referred everyone to the website of Stanford University to see their IBC policy. While he did not necessarily want to adopt this policy, he thought it was well presented and asked everyone to look at it.

RENEWALS WITH NO CHANGES TO PROTOCOLS:

1. DR. W. MICHAEL SCHELD (041-03) last visited 1/6/03. Previously approved for enteropathogenic E. coli, Streptococcus pneumoniae, S. aureus, S. anginosus, S. intermedius, Listeria monocytogenes, and Bacteroides fragilis. He was approved.
2. DR. GARY BALIAN (096-99) last visited 6/10/02. Previously approved for mouse and rabbit SCV, HIV transfected cells, adeno-associated virus, human endothelial cells, adeno-associated vectors, adenovirus and staphylococcus aureus. He was approved.
3. DR. TERRY TURNER (133-02) last visited 1/7/02. Previously approved for pTAT expression vectors. He was approved.

PROTOCOLS WITH NEW LAB VISITS:

1. DR. P. TODD STRUCKENBERG (160-03) last visited 12/12/03 by Hammar skjöld and Mann. He is currently approved for adenovirus and wants to add lentivirus vectors and human cell lines. He will infect Xenopus cell line -S3. He was approved.
2. DR. RONALD TAYLOR (049-99) last visited 12/12/03 by Feldman. He uses human and primate blood as well as Daudi and Raji cell lines. His work is associated with the following P. falciparum, S. pneumoniae, S. aureus, Paeruginosa, e. coli, Dengue virus 2-S1 strain, Shiga-like toxin II, and S. typhimurium. He has been working with blood for quite awhile. He needs to get us a copy of his lab plan for the BSL2 rooms. He was approved pending receipt of the lab plan.
3. DR. THOMAS E. BROWN (122-01) last visited 12/19/03 by Kiley. He uses methicillin resistant Staphylococcus aureus. He needed to send a signature page and it was sent. He was approved.
4. DR. STEVEN POWELL (040-98) last visited 12/17/03 by Mann. He uses H. pylori, human tissue and human cell lines. He needs to have the manual updated and Mike Smith, with whom he shares the BSL2 lab needs to do his IBC paperwork. Dr. Ernst volunteered to help him and to look in on his lab.
5. DR. WILLIAM WALKER (129-01) last visited 12/5/03 by Kiley and then on 12/18/02 by Leonard. He uses human tissue. They hadn't started actual work, but had the lab set up and they have an understanding of the biosafety issues. He was approved.

NEW PROTOCOLS:

1. DR. JAMES W. MANDELL needs a lab visit.
2. DR. ROBERT SONG needs a lab visit.

3. DR. SCOTT VANDE POL needs a lab visit. When we do his lab visit, we need to question him as to what he's putting into the papilloma virus.
4. DR. EDWARD A. BOTCHWEY needs a lab visit.

NEW BUSINESS:

1. Dr. Ernst wanted to know about the Hepatitis B policy. Dr. Guerrant has suggested that we should include Hepatitis A, especially for those persons who use gastro-intestinal tissue. There is a Hepatitis A and B vaccine that may be appropriate. There was a question as to if it has been licensed in the U.S. Dr. Mann said that she would find out and report.
2. Dr. Feldman said that he had another issue. In order to comply with the ALAC Evaluation Program, the University must register transgenic animals. The part of the IBC recombinant DNA regulations that apply in this case is Section III -e-3 on the guidelines webpage:
http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm
These are only those animals developed as human diseases models and the gene knockouts. The PI needs to present a map of the construct and be approved by the committee on paper. Currently the people to whom this applies are Sonia Pearson-White, Heidi Scrabble, Robert Granger, Serena Loo and Scott Zeigler. The committee needs to create a policy on this issue so that there will be a paper approval for these animals. There are also similar issues relating to Section III-E-2 for whole plants that have been modified.

The meeting was then adjourned.

UVA INISTITUTIONAL BIOSAFETY COMMITTEE MINUTES

February 2, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Susan Kiley, Thomas Leonard, Barbara Mann, and Mark Ross.

OTHER BUSINESS:

1. Dr. Hammarskjöld opened the meeting by telling the committee about the meeting with David Hudson and Tom Leonard. They discussed writing policies for the committee and she handed out the Stanford University IBC policies for everyone to review and make any corrections they believe it should have. We may want to include a policy on BSL3 building designs so that the committee can help get rooms that they can later approved easily. She also gave him the letter that she had received from the Sunshine Project since it's his office that gives information on the committee to the outside community. Drs. Leonard and Hammarskjöld reminded Dave Hudson that we need new members.
2. The committee resumed discussion of Dr. Ernst's inquiry about adding Hepatitis A to the requirements for human tissue or perhaps some human tissue. Dr. Dick Guarrant had raised this issue during an inspection. He believes it would be helpful to have people who work with digestive tissue in particular and perhaps all tissue have a Hepatitis A shot. Dr. Leonard told the committee that the Blood Borne Pathogens rules do not include Hepatitis A, but if the IBC or investigators feel that Hepatitis A vaccination is warranted for a particular project, it should be offered to individuals with potential exposure. Dr. Mann is going to look into what's practiced and ask the Infectious Disease people what they recommend.
3. Dr. Feldman told the committee about new plans for the BSL3 vivarium, which he is involved with renovating. He said that the air problems have been addressed and that emergency power has been added. He says that he is trying to secure money through grants to renovate the area. He hopes that the IBC can visit it and see if space can be created. He sees it as an area that non-airborne material could be studied. Dr. Kiley said that any new BSL3 spaces should be shared rather than having departments control the areas. The committee seemed to agree that it would be helpful if the institution had a plan for BSL3 use.

CHANGES TO PROTOCOLS:

1. DR. KENNETH BRAYMAN (157-03) wants to include additional viral vectors. His protocol was approved.
2. DRS. STEVEN M. POWELL and MICHAEL SMITH (040-96) was last visited 12/17/03 by Barbara Mann. Dr. Powell added Dr. Smith to his protocol and they've made their changes to the lab manual as required with the help of Peter Ernst. Their new protocol was approved.

RENEWALS WITH CURRENT LAB VISITS:

1. DR. BRENT FRENCH (073-98) was last visited 9/18/02. He was approved.
2. DR. BARBARA MANN/WILLIAM PETRI (002-96) was last visited 8/28/02 for BSL2 and needs a lab visit for BSL3. Their BSL2 work was approved.

PROTOCOLS WITH NEW LAB VISITS:

1. DR. DEAN KEDES (082-99) was visited by Drs. Mann and Leonard on 1/21/04. He mentioned taking cells into the microscope room and has given us an addendum for this. He also wants to have fixed cells that may be positive for HIV for use in BSL1. The fixed tissue is not considered an IBC issue since it is BSL1 under the regulations. His biosafety cabinets have been re-inspected. He was approved.
2. DR. ULRIKE LORNEZE (092-99) was visited by Drs. Mann and Leonard on 1/21/04. She was approved.
3. DR. ANDREI KHOKHLATCHEV was visited by Dr. Kiley and Dr. Leonard on 1/30/04. He was approved and given protocol number 167-04.
4. DR. ROBERT SONG was visited by Dr. Leonard 2/3/04. He was approved and given protocol number 168-04.
5. DR. SCOTT VANDE POL was visited by Dr. Leonard on 2/3/04. Dr. Hammarskjold said that she spoke to him about his vectors and he appears to have a good attitude about safety in more than just name. He was approved and given protocol number 169-04.

NEW PROTOCOLS:

1. DR. ZHYI ZUO wants to use human cell lines and needs to have a lab visit.
2. DR. KEVIN LYNCH wants to use venom from a Brown recluse spider (*Loxosceles reclusa*) and he wants to clone the enzyme (sphingomyelinase D)
3. HEIDI SCRABBLE wants to work with lentivirus and human cell lines.
4. KEVIN LEE wants to work with human adipo-derived multipotent cells.

The next IBC meeting will be Thursday, March 25 at 4:30 p.m.

The UVA IBC had no meeting in March 2004 due to conflicts with members being out of town and with illnesses. It was cancelled.

UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

April 1, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Thomas Leonard, Barbara Mann, and Mark Ross.

Dr. Hammarskjöld opened the meeting with a problem that had occurred right before the meeting involving her, Dr. Leonard, Dr. Joanne Lannigan, the operator of the Microbiology Flow Cytometry Core Facility and Dr. Tim Bender who is a Professor of Microbiology and the chairman of the supervising committee of the Core Facility. It had come to Dr. Hammarskjöld's attention that Dr. Lannigan was asking people who used the FACs to do HIV and Hepatitis C tests on their samples before giving them to her. Dr. Hammarskjöld was concerned that the tests were being done by each lab rather than an outside lab and that such testing may give Dr. Lannigan a false sense of security since there are so many other materials that could be in untested human samples that may be equally as infectious as those material tested. Drs. Hammarskjöld and Leonard said that the discussion was quite tense and there seems to be some animosity about the PIs who have brought human material. Dr. Bender said that he had heard from someone on the committee that we approved Dr. Lannigan using human materials at BSL2 level rather than at more stringent methods because of political reasons. He implied that the IBC was pressured into approving human materials at only a BSL2 level even though the human samples could contain BSL3 or higher infectious agents. Drs. Leonard and Hammarskjöld explained that all untested human tissue is used under BSL2 protocols. If it is tested and contains an infectious agent such as HIV then it would need to be used under BSL3 protocols. Both Drs. Hammarskjöld and Leonard tried to assure Drs. Lannigan and Bender that the committee objectively reviewed Dr. Lannigan's request to use human tissue. Further, David Easton, the former Biosafety Officer and Tom Leonard the current Biosafety Officer visited with Dr. Lannigan and found that she uses very good BSL2 protocols and that her hood has been getting regular certifications. Dr. Leonard feels that Dr. Lannigan is over zealous beyond what is reasonable for BSL2. However, everyone agreed that the Core Facility could put in place additional requirements. He did say that the IBC would find any open tubes to be against the BSL2 regulations and if Dr. Lannigan called, we should be available to deal with the PI who would be violating his own Lab Manual to transport material that way. Such activity should be reported to us. Dr. Leonard also said that there is a group with UCLA who publishes guidelines about how to work with Flow Cytometry and human tissue. She follows their recommendations. Both Drs. Leonard and Hammarskjöld have personally spoken to Dr. Lannigan about this matter in the past and told her to come to them if there is any problem, but she never approached either of them. It was decided that the IBC would again advise Drs. Bender and Lannigan that if someone comes with open tubes they can be rejected and should be reported to the IBC and that the Core facility should continue to have anyone who wants to have BSL2 samples done, their request should be given to Gloria Bowers who will verify that they have a current BSL2 approval.

Drs. Leonard, Mann and Hammarskjöld then reported that they attended a departmental meeting of the Biomedical Engineering Department with Dr. Skalak, the Chairman about the BSL3 lab located in the middle of their labs where Dr. Mann hopes to start work with *Francisella tularensis*. The department didn't have an extensive bacteriological background and had many questions about how *Francisella tularensis* is spread. It was a productive meeting.

Our minutes were sent to the Sunshine Project. This organization is giving grades for the minutes it receives. So far, UVA has not been graded.

Dr. Hammarskjöld advised the committee that HHS is discussing changes to enhance biosecurity for all labs, not only those with Select Agents. They are also writing guidelines for dual use research.

Protocols with new lab visits:

- A. HEIDI SCRABBLE (170-04) was visited 2/17 by Susan Kiley and Jean Gratz. Dr. Kiley gave a report to the committee asking for an expedited approval since the committee would not meet until 3/25/04. The committee agreed by the expedited approval by email 3/1/04.
- B. JOHN HERR (036-98) was visited by Susan Kiley and Jean Gratz on 2/17/04. Dr. Kiley gave a report to the committee asking for an expedited approval since the committee would not meet until 3/25/04. The committee agreed to the expedited approval by email on 3/1/04.
- C. JOHN HUNT was visited 2/17/04 by Susan Kiley and Jean Gratz. He would like to add human cell lines. He faxed the appropriate signature page as requested. Overflowing tissue culture dry waste was corrected. His lab was approved. He was given protocol number 171-04.
- D. WA'EL RIFAI (155-03) was visited 2/17/04 by Susan Kiley and Jean Gratz. He would like to add human cell lines. Dr. Rifai has advised me that he's called about getting his hoods re-certified. (They have not as yet expired.) His lab was approved.
- E. LARRY BORISH (115-00) was visited 3/3/04 by Peter Ernst. Dr. Ernst's comment on his lab was "A-OK" His lab was approved.
- F. SUN-SANG J. SUNG was visited 3/3/04 by Peter Ernst. It was suggested that he should be under Dr. Fu's protocol since he is using his Tissue Culture, however we haven't gotten a letter from Dr. Fu regarding this.
- G. KEVIN LYNCH (075-99) was visited 3/4/04 by Susan Kiley. He had a question about the FDA rule on LD50's in mice. His lab was approved and Dr. Feldman will speak to him about the LD50's.
- H. LISA PALMER (107-00) was visited by Susan Kiley. She wants to add human cell lines to her approval. Her lab was approved with the additional cell lines.
- I. CHARLES FLICKINGER (038-98) was visited 3/4/04 by Barbara Mann. This lab was in very good order. Her notes say that there were no problems with this lab. His lab was approved.

- J. ROY C. OGLE was visited by Tom Leonard and Jean Gratz on 3/22/04. He would like to add stem cells from lipoaspirates, bone cells from UVA and human fibroblasts from ATCC. He faxed his signature page to show the additional signatures. He gets his cells from Dr. Katz and it's believed that Dr. Katz is the lab that is giving out human cells without checking to see if the PI has approval to have them. Dr. Feldman asked that we have Dr. Katz come before the committee about dispersing human tissue without approval. Dr. Ogle's protocol was approved and he was given protocol number 172-04.
- K. LLOYD S. GRAY was visited by Tom Leonard and Jean Gratz on 3/22/04. There were no problems He was approved and given protocol number 173-04.
- L. CORRINE SILVA (055-98) was visited by Tom Leonard and Jean Gratz. Gloria said that she went there and her signs and lab manual had been corrected. Her lab was approved.
- M. KEVIN LEE was visited by Tom Leonard and Jean Gratz on 3/22/04. He was approved. He was given protocol number 174-04.
- N. CHRIS REMBOLD (006-99) visited by Tom Leonard and Jean Gratz. He needs to update his manual and have people who share his tissue culture sign his protocol. He emailed that he would have his lab manual for a week or so. His protocol was approved, but he can't have his approval until he shows us the manual.
- O. TIMOTHY BULLOCK (145-02) visited by Tom Leonard and Jean Gratz. He needed to add some of his new materials to his lab manual and remove a chair. Also he needed to get signatures from Dr. Mullens group and get CMC containers. Susan Kiley reported that he fulfilled all the items that Tom Leonard had asked him to do. He was approved. Dr. Kiley suggested Timothy Bullock as a new member. Everyone agreed that Dr. Hammar skjöld should pursue his nomination.
- P. JAMES MANDELL visited by Tom Leonard and Jean Gratz on 3/23/04. He wants to add tumor cell lines to his protocol. He needed to add his signs and stickers. Tom Leonard said that Jean Gratz had checked his lab and everything was done. He was approved. He was given protocol number 175-04.
- Q. RICHARD PEARSON (014-00) visited by Tom Leonard and Jean Gratz. Although Dr. Pearson is not currently working with his material he wants to keep it available in case he wants to work with it. He's the only one who would work with it at this time. He was approved.
- R. DENNIS TEMPLETON visited by Tom Leonard and Jean Gratz on 3/23/04. He wants to add some human cell lines. Also, he wanted the committee to know that he is using a strain of vaccinia that will not grow in mammalian cells (avian variant), which he got from Dr. Wagner. Therefore he doesn't feel that anyone in his lab needs a vaccine. His lab was revisited and Jean Gratz said that he was in good shape. He was approved. He was given protocol number 176-04.
- S. LUKAS TAMM visited by Peter Ernst on 3/24/04. He had his hoods certified and did his signature page. He was approved. He was given protocol number 177-04.

- T. ZHIYI ZUO visited by Tom Leonard and Jean Gratz. He sent us a description of the lentivirus he's using, however he hasn't completed the signs and lab manual. It was suggested that he and his lab should go to Tom Leonard's Biosafety training. He was not approved.
- U. FELICIA GASKIN (097-99) visited by Tom Leonard and Jean Gratz. She hasn't advised anyone that she has updated her lab manual. She was not approved until she has her lab manual updated.
- V. EDWARD BOTCHWEY visited by Tom Leonard and Jean Gratz on 3/24/04. He was revisited and his lab was fine. He was approved. He was given protocol number 178-04.
- W. M. MITCHELL SMITH visited by Tom Leonard and Jean Gratz on 3/24/04. His lab was approved. He was given protocol number 179-04
- X. GERALD BROWN is in Psychiatric Medicine and has requested approval to take salivary samples and send them to an outside lab to be tested. He stores the samples in Dr. Glenn J. McGarvey's laboratory while he collects samples. Per a visit by Jean Gratz, the freezer is properly marked as containing human material. His lab was approved. He was given protocol number 180-04.
- Y. BARBARA MANN was visited 3/10/04 at her BSL3 lab by Tom Leonard and Jean Gratz. Dr. Mann left the room before we discussed her lab. Dr. Leonard said that everything was in order. The CDC and the Department of Agriculture have previously inspected her and all of their comments have been positively addressed. Her protocol was approved for her to work with *F. tularensis* and *F. tularensis* LVS in the BSL3.

3) New protocols:

- A. JERROME P. FERRANCE uses human blood and cells of human origin. He needs to have a lab visit.
- B. BRIGIT WINTHER is doing a rhinovirus study May 7-12, 2004 similar to those of Drs. Hayden and Turner. In this study, objects will be infected with rhinovirus and they'll see if anyone contracts a cold. No hotel personnel will enter the room until after the study staff have washed down the surfaces with OSHA 299 which contains phosphoric acid (17%) and citric acid (4%) or with 10% Clorox. They will also treat the floors. The study was approved.
- C. ROBERT KADNER uses *Salmonella typhimurium*. He needs a lab visit.
- D. DONALD L. KIMPEL uses human blood, human tissue, sera and cell lines. He needs a lab visit.
- E. BARRY GAMBINER uses *E. coli*, recombinant adenovirus. He needs a lab visit
- F. ISA M. HUSSAINI uses adenovirus, Murine Leukemia Virus (MLV), cell lines. He needs a lab visit.
- G. ANGELA de S. OTERO uses human cell lines. He needs a lab visit.

4) Protocols to renew with no changes and who had a lab visit within the past 3 years:

- A. BENJAMIN GASTON (076-99) last visited 1/20/03. His protocol was renewed.

6) Protocols with changes:

- A. JEFFREY HOLT (142-02) was last visited 9/18/02. He's adding human tissue to his protocol. He needs a lab visit.
- B. JAMES P. LANDERS (126-01) was last visited 9/26/01. He is adding infectious agents to his protocol. He has had a needle stick. He needs a lab visit and he needs to do Tom Leonard's biosafety class.
- C. PETER LOBO (023-97) was last visited 8/25/00. He wants to do his HIV work in the multistory building, room 5099. He needs to do a lab visit and Dr. Hammarskjöld wants to go to this lab visit.
- D. CRAIG L. SLINGLUFF (127-00) was last visited 8/25/00. His protocol lapsed and has not been renewed for 2 years. He needs a lab visit.
- E. AMY L. TUCKER (118-01) was last visited 3/15/02. She wants to add adenovirus to her current protocol which was approved for human cells and human-derived cells. She needs a lab visit.
- F. JUDITH M. WHITE (080-99) was last visited 11/20/02. She wants to use cDNA encoding the Ebola virus VP40 protein. Her protocol was approved.

7) OLD BUSINESS

- A. J. JULIUS ZHU (135-02) was visited by Jean Gratz for the Biosafety Office and he did not appear very knowledgeable about his protocol. The committee wants to revisit him.
- G. ERIK HEWLETT (021-00) was last visited 9/3/03 by Drs. Kiley and Leonard. There were questions at the time Dr. Hewlett added the Sterne strain of Anthrax. We wanted to be sure he was not changing the strain to make it lethal and also to see why they needed to have people vaccinated. His changes were approved.

8) OTHER BUSINESS:

- A. Discussion of MR6. Richard Allen has asked for the IBC to comment on the building plans although the plans are not available to review. Barbara Mann told the committee that there are entirely new plans for the MR6. Dr. Mann will try to get the square footage of the BSL3 rooms for Dr. Hammarskjöld. It was decided that the IBC could not approve any plans until Richard Allen sent them to the committee.
- B. Universal hazard communication signs. Tom Leonard briefly showed new signs that would be going up in the research labs.
- C. Online IBC registration progress report. Problematic PIs and training program. Tom Leonard hopes to have Vaughn Kowahl present the new registration forms next Thursday, April 8.

9) Future meeting date was not yet decided.

UVA INISTITUTIONAL BIOSAFETY COMMITTEE MINUTES

May 6, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Gerald Hankins, Susan Kiley, Thomas Leonard, Barbara Mann, and Mark Ross.

Dr. Hammarskjöld opened the meeting by introducing Dr. Gerald Hankins, our new member. She also told everyone that Mark Ross, one of our community members, would be leaving the committee. She invited him to re-join the committee as a faculty member if he found himself working at UVa. She also told everyone else about other possible community members, Carl Schneitman and Ron Heizig who had been recommended.

PROTOCOLS WITH NEW LAB VISITS:

- A. JEFFREY HOLT (142-02) was visited 4/16/04 by Drs. Mann and Leonard. He had previously been approved for adenovirus and he added HEK cells, human auditory and vestibular hair cells to his lab. Both Dr. Mann and Leonard found his lab exceptional. He was approved unanimously.
- B. CRAIG SLINGLUFF (127-00) was visited 4/23/04 by Dr. Kiley. He wants approval for cells of Human Origin, vaccinia, EBV transformed B-cells, Melanoma cells and human cells lines. His cell lines are very numerous (102 pages). This prompted Dr. Leonard to say that we should probably get general types of cell lines from PIs rather than each specific line. Dr. Kiley said that his lab was very nice and his lab tech was especially talented. He was approved unanimously.
- C. BARRY GUMBINER was visited 4/27/04 by Dr. Leonard. He wants approval for E. coli, recombinant adenovirus and human cancer cell lines and human epithelial cell lines. He was fine and had no problems. He was unanimously approved.
- D. JAMES P. LANDERS (126-01) was visited 5/3/04 by Dr. Leonard. Both Dr. Landers and Ferrance were visited together. They had some open issues, which were still open at the time of the meeting. They need to clarify which infectious agents they are using, new signature pages with the Hepatitis B information, biosafety cabinet inspected, and signs placed. Gloria Bowers will contact them and ask them the status and remind them to do these items. Dr. Feldman said that he supplied them with most of their material and he would stop until they got their paperwork in order.
- E. JEROME FERRANCE was visited 5/3/04 by Dr. Leonard. See above.
- F. ZHIYI ZUO was visited 3/24/04 by Dr. Leonard and again on 5/6/04 by Jean Gratz who reported that everything was satisfactory. Tom Leonard said that there were serious problems when they were first visited but that they appear to have resolved the issues with the exception of the signature pages. However, he felt that this would be forthcoming and he recommended approving their submission. They were unanimously approved.

OLD BUSINESS:

JOANNE LANNIGAN (159-03) who was approved last year to work with human material under BSL2 conditions, met on 4/29/04 with Drs. Hammarskjöld, Leonard, Bender and Bill Knaus' group. Dr. Hammarskjöld said that there have been many discussions about sorting human cells with unknown potential infectious agents. Last meeting we had discussed that testing could be required, but it would have to be with an outside source. After Dr. Rekosh had been involved in this matter since he was asked to describe how to do testing for HIV, Dr. Hammarskjöld got emails from Dr Hogan and from Dr. Bill Knaus who said that the IBC was jeopardizing their funding on this project. Dr. Hammarskjöld suggested that we have a meeting with his group, Tom Leonard, Tim Bender who is the faculty director of the FACs and Joanne Lannigan. The end result is that Tim Bender and Joanne Lannigan said that they were willing to sort unknown human cells at BSL2, but wanted to upgrade their machine and their forms to conform with the usual practice in other FACs. Tom Parsons needs to approve this since it affects the Microbiology area of which he is the Chairman. Dr. Leonard has met with Drs. Tim Bender and Tom Parsons on this matter and reported that Dr. Parsons has accurate information on the matter. Under the new rules, PIs will have to disclose any known infectious diseases of the samples. Bender and Lannigan know that if there are BSL3 agents in the cells, the cells then become BSL3 and they can't be used in the facility. These new forms and rules will be on the FACs webpage. They will also refuse anyone who doesn't use containers within a container. Dr. Leonard said that the FACs facility needs to have the biosafety cabinet certified, and adopt written secondary containment requirements for presentation of human samples before they can proceed. The meeting also brought up the importance of a FACs facility in MR6 for both BSL2 and BSL3.

PROTOCOLS WITH NEW LAB VISITS:

PETER I. LOBO was visited 5/5/04 by Drs Leonard and Hammarskjöld. Dr. Lobo wants to work with HIV in a BSL2+ facility, which he wants to create in his current BSL2 lab. Dr. Hammarskjöld asked that we allow David Rekosh to join us in this discussion since he has a long history of working with HIV and received training at NIH for this work. Dr. Rekosh began by saying that one of the purposes of the anteroom used in BSL3 facilities is to give you a needed psychological change to working with the live HIV1 virus. Putting on the paper suite, the double gloves, booties, etc. reminds you that HIV is to be used with care and that this lab is the one place you need to work especially safely. He doesn't think that the BSL3 practices can be done in a lab that is otherwise used as a BSL2 lab. He also says that all equipment and surfaces are assumed to be contaminated in BSL3 although there is a daily decontamination procedure. He also said that he believes that the norm in the world of HIV is a BSL3 like BSL2+ facility in the Thaler Center. HIV does not need a full BSL3 since it is not an airborne disease so the air handling can be normal. Many companies use complete BSL3 labs for their HIV work for liabilities purposes. Dr. Leonard suggested that there are places where they work with HIV and it is a BSL2 facility where they use BSL3 practices. He felt that the NIH/CDC regulations indicate that one should be able to work with HIV in a BSL2 room with only

BSL3 practices that do not include a separate vestibule. Both Dr. Rekosh and Dr. Leonard had different ideas of what the practices should include. Dr. Feldman suggested that the more limiting rules should be used since HIV is a permanent disease and cannot be cured with drugs or vaccinated against. He said that he found the possibility of such a disease to require the greater regulation. Also, he said that the space exists so it isn't keeping Dr. Lobo from working with it. Dr. Leonard however said that the regulations are not the more limiting but the less limiting and that the regulations need to be followed so as to be fair to the PIs who read them. Dr. Hammar skjöld suggested that there were various interpretations of the rules and that the OBA allows more strict regulation at institutions, but not lesser regulation. Dr. Leonard still found that imposing greater regulation before advising PIs could be a problem. Dr. Kiley said that when she worked at NIH, they renovated the upper floor of a building for HIV and all the rooms had anterooms so that may indicate that the regulations are meant to be greater than Dr. Leonard believes. Although the committee could read the recommendations for BSL2 practices and spaces and BSL3 practices and spaces, there was no document that envisioned the combination of BSL3 practices in BSL2 spaces. As a result, most people seemed to agree that we can interpret this combination as we like. Before he left, Dr. Rekosh said that he never thought he'd be arguing for greater regulation since he feels that he spends much of his time trying to resist regulation. Dr. Feldman suggested that we vote to approve Dr. Lobo's BSL2+ laboratory that he made for all HIV work excluding the propagation of the virus. Dr. Barbara Mann and Dr. Tom Leonard voted no and everyone else voted yes. The proposal passed.

PROTOCOLS TO RENEW WITH NO CHANGES:

TOM G. OBRIG (079-00) was last visited 2/21/02. He was approved.

PROTOCOLS WITH CHANGES:

1. KENNETH BRAYMAN (157-03) was last visited 6/6/03. He has recently installed a cGMP cleanroom where he's doing islet isolation. It was noted that he has a very competent staff. He was approved without a visit.
2. JAMES ROCHE (111-00) is changing his space. He's sharing space with Dr. Guerrant. He needs a new lab visit.
3. ERIK. L. HEWLETT (021-00) wants to add some attenuated strains of anthrax. He was approved.
4. BARBARA MANN (002-96) wants work with (LVS) of *F. tularensis* in the BSL2 lab located in MR4 room 2127. Currently they are approved to work with this strain in the proposed BSL3 lab, and since they will start working in the BSL3 lab with Francisella, they'd like to take the *F. tularensis* back to the BSL2 room. She was approved.

NEW PROTOCOLS:

1. SHYR-TE JU needs a lab visit.

2. SCOTT O. ZEITLIN has notified the committee, per NIH recombinant DNA Guidelines requiring simultaneous IBC notification, that he is generating with transgenic rodents. He was approved.
3. THERESA GUISE needs a lab visit.
4. JOHN W. CHIRGWIN needs a lab visit.

OTHER BUISINESS:

1. Vaughn Kowahl was not able to present the IBC online registration, however, Tom Leonard told us that it was developing nicely on a conceptual basis, and that he would present it during the next meeting.
2. The committee had been emailed a copy of the clinical research proposal to be distributed to prospective researchers and everyone needs to review the role of the IBC and get any corrections or changes to Tom Leonard as soon as possible.
3. The committee saw the proposed charter for the National Science Advisory Board for Biosecurity that has been announced. It proposes to change the oversight of the IBCs. It also talks about dual-purpose research.
4. Barbara Mann told the committee that she polled doctors in ID to see if they thought that Hepatitis A vaccines should be required for people working with human cells. No one could find a reason to be vaccinated against Hepatitis A unless they were actually working with GI samples and since Hepatitis A is an acute infection they are unlikely not to know about the infection. It does appear to be a safe, good vaccine. She suggested that we require Hepatitis A vaccines on only selected cases, which may suggest such a need. The committee agreed.
5. The IBC Charge document is still in rough draft form.

The next meeting will be June 10, 2004 at 4:30 p.m. in Jordan Hall room 7100.

UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

May 12, 2003

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Barbara Mann, Peter Ernst, Sanford Feldman, Susan Kiley, and Marjorie Maxey.

1) OLD BUSINESS

- A. The minutes from April 14, 2003 were approved unanimously with corrections. Also, the committee decided Gloria Bowers should email the minutes to the committee for approval right after the meeting. This is to enable us to approve the minutes outside of the meeting.



- C. Dr. Hammarskjöld told the committee that she has finally spoken to someone from OBA about our FACs Core. He was familiar with the brand of FACs machine we are using and the problem with the aerosols. He said that he felt that BSL2 was sufficient for human tissue unless it's known to be more infectious. He also said that testing is not always meaningful so at least universal precautions or BSL2 should be used. If there are larger samples or samples similar to HIV, then you should work with them as BSL2+ (BSL 3 procedures in a BSL2 room). He didn't think that there needed to be changes to the air pressure. Furthermore he said that this machine produces large droplets and that they should fall from the air faster. The operator should let the air clear before continuing with the procedure.

- D. The Texas Tech University case involving Dr. Thomas Butler and the plague samples is continuing. The Wall Street Journal had a substantive article outlining the case. Dr. Butler is still not permitted to leave the county where he lives or to speak to anyone related to his case. It does not appear that many scientific organizations are coming out with any opinions on the case.

3) NEW PROTOCOLS AND RENEWALS:

- A. DR. JAMES REIBEL has never had a protocol. He needs to be approved for a special class he's doing on June 6. We need to see what kind of lab manual he's giving out to the attendees and to see where he'll be doing the work. We should look at the lab before the class.
- B. DR. M. MITCHELL SMITH needs a lab visit.
- C. DR. JESUS RIVERA-NIEVES needs a lab visit. There was some discussion about schistosoma.
- D. DR. JERRY NADLER (136-02) was last visited 12/12/01. He was approved without a lab visit. He did not appear to have any substantive changes.
- E. DR. BARBARA MANN has given us her BSL3 protocol and the lab manual is available to review before her lab visit. She told the committee that the work on her lab is completed. She wants to start work in her BSL3 under BSL3 protocols using the live vaccine (LVS) strain of *F. tularensis* to gain experience in the procedure. LVS is considered a BSL2 agent. They've been tested for their respirators and are set to start. Several committee members wanted to know if this room would be just temporary since Dr. Skalak has opposed it. Dr. Mann said that Judy Mareta is still looking into trailers. Also, if Dr. Petri's proposal for UVA to become an Infectious Disease Center, she would move into the new facilities when they became available. Several committee people expressed their reservations about the trailers and modular buildings. There is concern about the ability to secure them. This also led to a discussion about the futility of buying the modules and then applying to the IBC who would then feel pressure to approve a facility that was already here. Then, it was decided to do a lab visit for Dr. Mann and Susan Kiley, Peter Ernst and Marie-Louise Hammarskjöld asked to do the visit.

5) PROTOCOLS WITH NEW LAB VISITS:

- A. DR. MARTIN A. SCHWARTZ was visited by Kiley and Hedrick on April 30. He uses adenovirus and retrovirus. Dr. Kiley reported that the lab visit went very well and he was approved. His number will be
- B. DR. ADRIAN GEAR was visited by Kiley and Hedrick on April 30. He uses blood. He didn't have any problems and his visit went well. He was approved and his IBC number will be
- C. DR. DAN THEODORESCU (086-99) was visited by Kiley on May 8. His lab was in good order. He has a very competent lab manager. The committee approved him.

6) The next meeting will be June 2, 2003.

UVA INISTITUTIONAL BIOSAFETY COMMITTEE MINUTES

June 20, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Gerald Hankins, Susan Kiley, Thomas Leonard, Barbara Mann, and Marjorie Maxey.

1) Protocols with new lab visits:

- A. JAMES LANDERS and JEROME FERRANCE was visited 6/2/04 by Thomas Leonard and Jean Gratz. Their approval had been tabled until they had finished a new lab manual and proper signs. Jean Gratz has been to the lab and reported that everything was finished. They were approved unanimously.
- B. ISA HUSSAINI was visited 6/2/04 by Dr. Leonard and Jean Gratz. A follow up was done 6/8/04 by Jean Gratz. Dr. Hussaini uses adenovirus, Murine Leukemia Virus (MLV), cell lines 51 MG, U1242, U373MG, U87MG and human body fluid. Everything in their lab is now in order. He were approved unanimously.
- C. AMY TUCKER was visited 6/3/04 by Dr. Kiley. Dr. Tucker is adding human cell lines and adenovirus which she intends to put into animals to her protocol which is currently approved for human derived monocytes and macrophages. Dr. Kiley said that everything was in order and that she only had a question about the adenovirus being injected into animals on an open bench. Tom Leonard said that she would be working with the animals a short time and that there wasn't any problem using the adenovirus and that he hoped that there wouldn't be any problem with the allergens. She was approved.
- D. ANELADE S. OTERO was visited 6/3/04 by Drs. Leonard and Hankins and Jean Gratz. Her lab was good. She uses human cell lines and had a few items that needed updated and they were done. Gloria Bowers went down and checked her lab manual. However, there was a question of IBC policy. She wanted to take her cells to her main lab and fix them with 4% formaldehyde so she can use here fume hood. It was noted that 4% fomaldehyde solution did not require the use of a fume hood. If she removed the medium and rinsed the cells in her Tissue Culture, she would be able to move the cells to her main lab without BSL2 labeling. The committee wants to suggest that she do this to avoid the problem of making her other lab BSL2 while the unfixed cells are there, This way no BSL2 waste would be created. She was unanimously approved.
- E. DONALD KIMPEL was visited 6/3/04 by Drs. Leonard and Hankins andd Jean Gratz. Dr. Kimpel uses human derived cell lines, human sera and tissue. Dr. Kimpel had some issues to resolve with his chair, labels and transport box, but he did everything before the meeting. He is part of Dr. Fu's department and they have one manual for their Tissue Culture room. Some of the people who use this room collaborate and some do not. It's unclear how they are related. The committee needs more information as to the people who use the

room since it may make sense to have one manual. However, Dr. Kimpel was unanimously approved.

- F. TERESA GUISE was visited 6/3/04 by Dr. Leonard and Jean Gratz. Dr. Leonard asked to do Dr. Guise and Dr. Chirgwin together since they share facilities. They use human cell lines. Everything in their lab was in great shape. They were both unanimously approved.
- G. JOHN CHIRGWIN was visited 6/3/04 by Dr. Leonard and Jean Gratz. See above.
- H. JAMES K. ROCHE was visited 6/3/04 by Dr. Leonard and Jean Gratz. Dr. Roche wants to use *C. parvum* oocysts and will inject animals in MR4. He was approved unanimously.
- I. SHYR-TE JU was visited 6/10/04 by Dr. Leonard and Jean Gratz. Dr. Ju uses human cancer cells and cell lines. He is also a researcher who uses Dr. Fu's tissue culture. He was asked to prepare his own lab manual since he also uses a room other than the Fu lab. He was approved contingent upon a satisfactory lab manual. NOTE: 6/11/04 Jean Gratz visited Dr. Ju and said that his lab manual was fine.

NEW PROTOCOLS:

- A. JOSEPH HAN/STEPHEN PARK has given us a protocol for a class they are giving. They need a lab visit.
- B. DEBORAH A. LANNIGAN She needs a lab visit.
- C. WEI YUE They need a lab visit.
- D. SUSANNA KELLER She needs a lab visit.
- E. SUSAN KILEY She needs a lab visit.

PROTOCOLS TO RENEW:

- A. KODI RAVICHANDRAN (069-98) was last visited 10/22/98. He needs a new lab visit.
- B. THOMAS A. E. PLATTS-MILLS (134-02) was last visited 3/14/02. His application showed no changes and he was approved.
- C. GARY OWENS (089-99) was last visited 4/1/02. He was approved.

PROTOCOLS WITH CHANGES:

- A. TOM OBRIG (079-00) was last visited 1/29/03. He wants to add a second protein (ricin) to his IBC protocol. The committee wants to do a lab visit.
- B. GEORGE V. VERGHESE (166-03) was last visited 10/30/03. He wants to add cell lines and some human tissue. The committee wants to do a lab visit.
- C. GERALD HANKINS (067-98) was last visited 3/7/01. He wants to add cell lines and human cells. He was unanimously approved.

NEW BUSINESS:

- A. INB online registration and database progress. Vaughn Kowahl, who does our website has hired an assistant.
- B. Status of Bloodborne pathogens programs. Tom Leonard has taken over doing the Bloodborne Pathogens Class for researchers. We have, in the past, relied on Heidi Flannigan from the hospital to do these classes and used the Biosafety Officer's class for those people who were having problems. Heidi Flannigan has resigned from doing the OSHA classes and Barry Farr who is in charge of the hospital safety program is retiring. This seems to be a good time to pick up the training for OSHA and IBC. Tom Leonard is going to expand the training he already does to include all of the OSHA requirements for the Bloodborne Pathogens as well as give an overview of the Biosafety Program. Everyone was pleased to have something geared toward research.
- C. ACUC policy for Biological Agents in Care and Use of Animals. Tuesday, the ACUC is going to finalize their policy. It will mean that the IBC will approved the use of the biological agents, but that the ACUC will give the final limits once the infectious items are put into the animals. Everyone agreed with this. There will be continuity between the ACUC and the IBC.
- D. Transgenic Rodent Registration. We have asked that Sonia Pearson-White add information to her forms to get people to register with the IBC if they generating transgenic animals. We want to get everyone who is asking to make transgenic animals.
- E. Dr. Leonard says that the new Biosafety member, Jean Gratz is working out very well. She used to work in the Pathology lab in the hospital and is very familiar with infectious agents and laboratories. Dr. Leonard hopes she can help with the lab visits and creating a better training program. He's hoping to hire someone else too. She's been very useful with the ACUC and he asked the committee if they thought she should be a full time IBC member also. Dr. Hammarskjold thought that she would be very welcome to meetings, but that she should be an ex officio member. Everyone agreed to wait and see if she would have a particular need on the committee.
- F. Tom Leonard also said that he had two people to suggest for the committee, Carl A. Schnaitmann and/or Ron Herzig for the community member. Dr. Hammarskjold said that she'd speak to them.

NEXT MEETING:

The next meeting will be Tuesday, 7/15.

UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

July 15, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Sanford Feldman, Gerald Hankins, Ron Herzig, Susan Kiley, and Barbara Mann. Dr. Hammarskjöld opened the meeting by introducing the new community member, Ron Herzig and asking everyone to introduce themselves to Dr. Herzig. Dr. Hammarskjöld gave a description of IBC's and their relation to NIH and how our IBC operates. She explained that there is no formal training for members as of now, but that there are many changes that seem to be on the horizon for IBCs since the Patriots' Act.

Dr. Feldman asked that we have the agenda and the accompanying documents sent out to everyone before the meeting. Everyone assented to that idea and it was agreed that Gloria Bowers would do that starting the next meeting.

Protocols with new lab visits:

- A. DEBORAH LANNIGAN was visited by Dr. Kiley on 6/24/04 and was approved by email on 6/30/04. Her protocol number is 192-04
- B. SUSAN KILEY was visited by Dr. Mann on 6/18/04. She left the room before the description of her lab visit. Dr. Mann said that her lab was in very good order and her protocol was approved unanimously. She was given protocol #193-04
- C. WEI YUE was visited by Dr. Leonard on 6/24/04. He sent an email advising everyone that the lab was in good order and recommending approval. Her protocol was approved and given protocol #194-04.
- D. GEORGE VERGHESE (166-03) was visited by Dr. Kiley on 6/24/04. He had previously been approved to store material, but now he wanted approval to conduct work on human tissue and human cell lines. His lab was in very good shape. He was approved unanimously.
- E. TOM OBRIG (079-00) was visited by Drs. Kiley, Leonard and Hankins on 7/2/04. Dr. Kiley reported that the lab was in good shape. She said that Dr. Leonard had been concerned about the amount of material they would have and that Dr. Obrig assured everyone that it was well below the amount over which we would have to treat it as a select agent. No one had that information. Dr. Ernst was concerned to know if it was part A or B or the toxin that would be used and no one knew, nor had we known that this was a possibility. Dr. Kiley suggested that Tom Leonard may have known. Dr. Kiley said that Dr. Leonard had also been concerned that in the form in which the ricin would be used. He preferred that it be in solution. Dr. Obrig said they may not be able to get it in that form, but that he agreed that it was safer in solution and that he would have it put in solution as soon as it was received. Approval of the ricin was delayed pending getting the information on which part of the ricin they were using and what the LD50 of ricin is.

- F. KODI RAVICHANDRAN (069-98) was visited by Barbara Mann and Jean Gratz on 7/15/04. Dr. Mann reported that everything was in good order. He hadn't had everyone sign the acknowledgement page and indicate if they had a hepatitis vaccine, but he faxed it and it just needed to have the people who didn't have the vaccine indicate that they declined. He was approved unanimously. Dr. Mann also wanted everyone to know what she had learned from Jean Gratz about pasteur pipets. These have to be handled as sharps when they have been used with any biological material. If they're used with a saline solution, they can be treated as glass, otherwise, they need to be treated as a sharp and put in a sharps container. It's part of a Virginia law. Susan Kiley said that it was very similar in New York. Dr. Mann said that she wanted everyone to know in case they do any lab visits. There was some discussion as to how to get this information disseminated. Gloria Bowers suggested that Dr. Leonard and Ms. Gratz were preparing a new lab manual and registration document and that this information would probably be included there. It was decided that we should ask Dr. Leonard about this when he returns.

New Protocols:

- A. JEHPING LIU advised us that their lab is working with transgenic mice and recombinant DNA. We approved this protocol unanimously and its protocol number is 195-04.
- B. BRYCE M. PASCHAL wants to use adenovirus, retrovirus and human cell lines from ATCC. He needs a lab visit.
- C. CHRISTOPHER D. WILLIAMS wants to use human endometrioma cyst fluid. He needs a lab visit.
- D. MASUMI ETO wants to use recombinant adenovirus lacking a replication E1 gene. He needs a lab visit.
- E. DAVID M. SMALLEY wants to use human bodily fluids and tissues. He needs a lab visit.

Renewal protocols:

- A. JERRY L. NADLER (136-02) was last visited 12/12/01 and is adding lentivirus to his protocol. He needs a lab visit.
- B. DAN THEODORESCU (086-99) was last visited 5/8/03 and is adding established cell lines of human origin. Dr. Kiley recalled visiting him and said his lab was in good shape. His protocol was approved unanimously.

Protocols with changes:

- A. ISA M. HUSSAINI (186-04) was last visited 6/2/04 and is adding two new human melanoma cell lines and a collaborator who will sometimes work in his lab. He was approved unanimously.
- B. RAGHU MIRMIRA (131-02) was last visited 8/30/02 and wants to add human pancreatic islet tissue. He was approved unanimously.

- C. RONALD TAYLOR (049-98) was last visited 12/12/03 and is moving his lab to temporary quarters. Everyone decided that he needs a lab visit.
- D. SHU MAN FU (085-99) was last visited 1/29/03 and is adding Jordan Hall room 2213 to his protocol. He needs a lab visit.
- E. GREGORY A. HELM (051-98) was last visited 7/18/01 and is adding additional cell lines. He needs a lab visit.

New business:

- A. Dr. Mann discussed that changes that she and Dr. Leonard are asking to be made in the plans which we received from Richard Allen. Apparently we have gotten onto Richard Allen's list. A list of the comments prepared by Dr. Mann is attached as an addendum to these minutes. It's still unknown if the BSL3 space will be departmental or institutional. Aside from the comments on the floor plans, Dr. Feldman reminded everyone about the entire space being on a flood plane. Drs. Mann, Kiley, Feldman and Leonard will keep the committee apprised of the situation.
- B. The next meeting will be August 19 at 4:30 p.m. in Jordan Hall room 7100.

UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

August 19, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Gerald Hankins, Ron Herzig, Susan Kiley, Barbara Mann, Tom Leonard, Marjorie Maxey, and a visitor from Environmental Health, Vaughn Kowahl. Dr. Hammarskjöld opened the meeting by introducing Vaughn Kowahl to the committee and then Mr. Kowahl presented the new IBC declaration process, which will be going out in the fall. However, he also told the committee about the new registration process that will be all web based and he passed out an outline for the committee to review. However, they hope to have the 2005 registration entirely online and joined to the ACUC registration so that nothing will be redundant and that each committee will know what the other committee has approved. Also, they hope that committee members can then get direct access to the protocols online and will be able to read them before meetings. Also, whenever questions would arise, there would be access to exactly what is approved and what is coming up. Regarding BSL2 and BSL3 designation, the number can remain the same and the approvals will be online to see. This new web form will allow information to be easily available for the Biosafety Officer. Everyone thought it would be appropriate to have a hard copy for the files. Vaughn Kowahl hopes to have something online for the committee to see how it will work in the next few months. Everyone was very excited about the changes.

Protocols with new lab visits:

- A. RONALD TAYLOR (049-98) was visited by Gratz and Kiley on August 5, 2004. He needed approval for his temporary laboratory. He needed some signatures on his lab manual. Gloria Bowers had seen the new signatures. He was recommended for approval and approved unanimously.
- B. BRYCE PASCHALL (196-04) was visited by Gratz and Leonard on August 5 and 17, 2004. His lab impressed everyone and Dr. Leonard said that Dr. Paschal had very good questions about waste. He suggested that we ask him to be part of the committee. He was recommended for approval and approved unanimously.
- C. SHU MAN FU (085-99) was visited by Gratz and Leonard on August 10. He was adding a room in Jordan Hall to his protocol. He was recommended for approval and approved unanimously.
- D. JERRY L. NADLER (136-02) was visited by Leonard on Augusts 10, 2004. Everything was in order, except for signs. Jean Gratz went back and confirmed that their signs were in order. He was recommended for approval and approved unanimously.
- E. MASUMI ETO (197004) was visited by Leonard on August 10, 2004. Dr. Eto uses Dr. Brautigan's space since Dr. Eto is an Assistant Professor for Research. The committee asked that Dr. Eto have Dr. Brautigan's name on the protocol since Dr. Eto works in Dr. Brautigan's space. Dr. Eto had given the committee a protocol, which Dr. Brautigan had co-signed. Everything was in

order and the protocol was recommended for approval and the committee approved the protocol unanimously.

- F. GREGORY HELM (051-98) was visited by Mann on August 16, 2004. The space that Dr. Helm uses is in the Center for Comparative Medicine in MR4 and MR5. He stores the viruses he uses in Dr. Hankins' space and brings them over to the animal rooms. They bring a box with signs and the lab manual so that they can set up the room. We looked at room G144. Everything was in order and he was recommended for approval and approved unanimously.

New Protocols and protocols with changes:

- A. MARTIN SCHWARTZ (150-03) wants to add cell lines to his protocol. He was just recently visited this spring. He was approved unanimously.
- B. ROBIN FELDER (039-97) was last visited 5/21/01 and has a new lab. He needs to have a new lab visit.
- C. JOANNE LANNIGAN (192-04) wants to add unfixed human samples to her protocol. She has approval for human cell lines and human tissue, but she wants to label it BSL2+ for her human samples. Tom Gardiner has recently checked her biosafety cabinet. Jean Gratz and Gloria Bowers checked on it before the meeting. Several people had objections to calling the human samples BSL2+ since they are BSL2 and there should be no confusion about the samples. We will ask her to refer to the samples as BSL2. There should be no BSL3 samples in her lab. Dr. Ernst objected to the questions about the identity of the samples and believes the questions are not proper as they are stated for HIPAA (Health Insurance Portability and Accountability Act). He suggests that they get guidance from HIC. He says that if the trainee knows that the sample has HIV or Hepatitis, it's illegal to tell anyone. It was also suggested that she add Tuberculosis to her list since it's probably as common as the other items. Also, it was suggested that they end the process at the question, if the sample is not BSL2.
- D. JIN-ZHONG LI is taking Dr. Hankins place in overseeing Dr. Helms' work. We need to set up a lab visit and get a more comprehensive protocol. He is an Assistant Professor of Research similar to Dr. Hankins. Dr. Helms does all the in vitro work and Dr. Li (previously Dr. Hankins) does all the cell work. We need to set up a lab visit.
- E. TOM OBRIG (079-00) was approved by an email vote for using Ricin under BSL2 conditions. He is now asking to add Dr. John K. Hayes and Dr. Hayes' rooms 1765 and 1765A to his protocol. Dr. Hayes is an Associate Professor. The committee decided that Dr. Hayes should pursue his own protocol.

Other business:

- A. We discussed the question of how to deal with junior and senior researchers and how they give us protocols. In the above case of Drs. Eto and Brautigan, it was decided that Dr. Brautigan should co-sign the protocol since the space belonged to Dr. Brautigan and everyone in the space answered to him. He

would be in a better position to be responsible for the activities in his space. Along with the policy of having the “owners” of space co-sign protocol, the committee adopted the ACUC policy on the definition of faculty for principal investigator eligibility on IBC protocols. A copy is added below as an addendum.

- B. Dr. Mann and Dr. Leonard gave everyone a list of the BSL3 design comments that they had given to the MR6 committee. The committee was particularly concerned about the BSL3 animals being housed in the basement of a building that was being built on a flood plane. Everyone in the committee wanted them to know that they would be willing to be involved in this matter if Dr. Mann or Dr. Leonard wants us to do so.
- C. The next meeting will be Monday, September 13 at 5:00 p.m. in Jordan Hall room 7100.

ADDENDUM

POLICY ON THE DEFINITION OF FACULTY FOR PRINCIPAL INVESTIGATOR ELIGIBILITY ON ANIMAL RESEARCH PROTOCOLS

Purpose:

The purpose of this policy is to define who is eligible to act as a Principal Investigator (PI) on an animal research protocol at the University of Virginia.

Policy:

Only elected members of the UVA faculty* may act as a Principal Investigator on an animal research protocol submitted to the Animal Care and Use Committee. A letter of appointment from the UVA Rector and Board of Visitors is considered verification of faculty rank. The elected members of the faculty include:

- Professors
- Associate Professors
- Assistant Professors
- Instructors and Lecturers
- Any of the above titles in conjunction with the word "Research" (e.g. Research Assistant Professor, Associate Professor of Research)

The following members of the professional research staff are **not** considered faculty and are not eligible to act as a PI on an animal use protocol:

- Research Assistant
- Research Associate
- Research Scientist
- Senior Scientist
- Principal Scientist

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*\*University of Virginia, Financial Policies and Procedures,  
Grants and Contracts Policy VIII.A.1, Section 2.2*

## UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

September 13, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Susan Kiley, Barbara Mann, Tom Leonard, Marjorie Maxey, and a visitor from Environmental Health, Vaughn Kowahl.

Dr. Hammarskjöld opened the meeting by introducing Vaughn Kowahl to the committee and then Mr. Kowahl presented the advances he'd made with the new IBC declaration process, which we hope to have out in late October. The new declaration is web based and will be entirely on line and will be joined to the ACUC registration. He hopes to remove any redundancy between the two protocols. There was some discussion of how we should send out the emails to alert people to renew or do a new declaration. We discussed the possibility of staggering the emails so that we would not have everyone reply at once. It was suggested that we send them out by department or by a geographical area. It was also suggested that it be alphabetical since it may be difficult to get good lists of department faculty. Vaughn will show us the final process by 10/13 and then the notices will go out within a week. We discussed how to be sure that we're getting the entire new faculty, but could not find a way to get everyone.

### Protocols with new lab visits:

- A. DAVID SMALLEY uses human body fluids and tissues. He was visited by Mann on 8/23/04. His lab was in good shape and he had everything in order. He was unanimously approved and his number will be 197-04.
- B. CHRISTOPHER D. WILLIAMS uses human endometrioma cyst fluid and was visited by Leonard and Gratz on 9/1/04. He only had a freezer to inspect since he does animal work. His manual was in good shape and he had everything in order. He was unanimously approved and his number will be 199-04.
- C. JIN ZHONG LI uses adenovirus, AAV and human cells and cell lines. He was visited by Leonard and Gratz on 9/1/04. He is replacing Gerald Hankins. He had some questions about rooms and needed some signs. Jean Gratz re-visited him. He had resolved any problems we had with him. He was unanimously approved and his number will be 198-04.
- D. ROBERT KADNER uses *Salmonella typhimurium*. He was visited by Leonard and Gratz on 9/13/04. He has a post doc, Igor Olekhovich who was in charge of the *S. typhimurium*. There was a discussion about if the *S. typhimurium* was actually BSL2, but they didn't have any citations to change it. Dr. Mann said that even when there are vaccine strains, she would need more information before she would be willing to allow it to be used as BSL1. Dr. Leonard said that there didn't seem to be a problem with that since Dr. Kadner himself seemed happy for it to be BSL2. There were however some questions with separating the garbage and Dr. Leonard wants them to contact Jean Gratz to be sure that they are doing

things properly before he asks for their approval. Their protocol was tabled.

- E. ROBIN FELDER (039-97) uses human fluids and primary cells and cell lines from humans. He was visited by Leonard and Gratz on 9/13/04. He also asked us to look at a potential new BL2 lab for a microscope, but without water. Their lab was stellar and there were no problems with anything. He was approved unanimously and his number remains 037-97. This lab had another question. They have a room that they would like to make into a BSL2, but it doesn't have a sink. It will have a biological safety cabinet, an incubator and a microscope. Dr. Leonard said that he thought they could use some antibacterial wash on the wall for everyone (a hand sterilizer) and write the manual in that room to direct everyone to go outside and wash after using the room. He also said that he felt that this should be a case-by-case decision and that in this lab's case in particular, he felt they would work well and follow the rules. Dr. Kiley agreed that there are some labs at UVa, which may not have water in the lab, but have it in the outer lab, and she also felt that this should be allowed in this case. So the committee agreed that they could go forward with this room and make it a BSL2. Peter Ernst left since he had another engagement.

#### New Protocols and protocols with changes:

- A. GEORGE S. BLOOM (122-01) was last visited 8/24/01. He uses adenovirus and human cell lines (i.e.: HeLa, etc.) He needs a 3-year lab visit.
- B. G. PAUL MATHERNE (083-99) was last visited 7/23/03. He uses replication deficient adenovirus type 5. He only had changes in personnel. He was approved.
- C. JOHN K. HAYES wants to use Shiga and Ricin toxin. His protocol is new and needs a lab visit.
- D. David W. Mullins wants to use vaccinia, T cells and tumor lines of human origin. He has a new protocol and needs a lab visit.
- E. SHAYN PEIRCE-COTTLER wants to use human adipose-derived stoma cells. He has a new protocol and needs a lab visit.
- F. AMY H. BOUTON (074-99) was last visited 7/24/02 and she uses *Yersinia enterocolitica*, *Yersinia pseudotuberculosis*, retroviral vectors for infection of mammalian cells, cDNA encoding the glycoprotein (GP) of Ebola virus, Vesticular Stomatitis Virus Indiana strain and human cells lines. She has added Ebola virus like particles and human cell lines. She is also adding two "shared" rooms. She needs a new lab visit since she is adding rooms.
- G. BARBARA MANN (002-96) wants to add *Cryptosporium sp* to her protocol. Dr. Mann explained what she wanted to do with the *Cryptosporium*. She would be using it in a part of her lab where there would be the fewest people. She would be getting it from Dr. Guerrant and would not be storing it or growing it. She left the room so we could

discuss her protocol. Everyone agreed that she understood how to handle it. She was approved unanimously.

- H. JOANNE LANNIGAN (159-03) has changed her lab manual to read BSL2 agents and changed the wording on her forms. Everyone was concerned that Dr. Ernst was happy with the wording of the forms. Gloria Bowers said that she had gotten an email from Dr. Ernst in which he said that the forms had been corrected. The wording was changed to refer to unknown human tissues as BSL2 and not BSL2+. Her protocol was unanimously approved.

Other business:

- A. Dr. Feldman, Dr. Mann and Dr. Leonard said that they thought that the changes from Dr. Mann and Dr. Leonard had been accepted for the new building, MR6.
- B. The next meeting will be Monday, October 4 at 5:00 p.m. in Jordan Hall room 7100.

## UVA INISTITUTIONAL BIOSAFETY COMMITTEE MINUTES

October 10, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Susan Kiley, Ron Herzig, Tom Leonard, Marjorie Maxey, and a visitor from UVA's Auditing Department, Karen Eldridge.

Dr. Hammarskjöld introduced Karen Eldridge from the auditing Department to the committee and the committee introduced themselves to her. Ms. Eldridge was present to audit how the IBC process occurred at the University. Dr. Hammarskjöld described IBC rules to Karen and informed the committee about the Sunshine Committee that requested copies of our IBC minutes, which we provided last February. The Sunshine Committee just today issued a report ranking national IBC's based on what they learned from the minutes as well as how different institutions responded to the request. UVA was in the portion of the report on IBC's described as adequate, the highest approval rating. Only 4% of the IBCs fell into this group. Karen Eldridge asked what the IBC thought they needed to function better. Ms. Eldridge also suggested that the IBC database be cleaned up before we used it to make new registration requests. PIs and others, who have left the institution, but remain in the database. Ms. Eldridge stated that she was preparing a report on the committee, which would go to the Board of Visitors, Ariel Gomez, OEHS and Dr. Hammarskjöld. Ms. Eldridge hoped it would be used to gain more support from the administration for the committee. There was a lively discussion of how to make the IBC more visible to the research community. It was suggested that the University should have a mandatory orientation session for new researchers providing information about performing research at UVA, the regulatory requirements for biohazardous work, function, and submission of information to the IBC. Also, the Office of Sponsored Programs should be consistent in requiring everyone to have IBC approval that submit grants containing biohazardous agent work, and that infraction of IBC requirements may result in loss of grant funds. The IBC should probably be planning for possible human Gene Therapy protocols, which take lots of time and energy. Everyone agreed that we should try to have our system working as well as possible so that as the workload increases, the system will be prepared to undertake all of the new and additional needs. Karen Eldridge thanked everyone for his or her time and left the meeting.

Dr. Hammarskjöld started with the problem of Dr. Okonkwo who had inadequately labeled an animal cage as ABSL2. Dr. Okonkwo has no IBC protocol, but has his own ACUC protocol and is listed as an animal handler under Dr. Lee's protocol (174-04). Dr. Lee, who is approved to work with human adipose-derived multipotential stem cells, put human stem cells into rats for Dr. Okonkwo, gave the rats back to Okonkwo who subsequently housed them in the Old Medical School vivarium under Okonkwo's name and animal protocol number. However, the cages were labeled stem cells ABSL2 and did not specifically state the precautions to be taken in handling them. They later were interpreted by the vivarium staff as having been inoculated with an adenoviral gene vector and so no longer housed under ABSL2 conditions after 72 hours. This was a

potential risk to people who handled the animals without proper protection. The ACUC has suspended all of Dr. Okonkwo's protocols. Okonkwo is currently outside of the country for a period of over one year. (He's a medical doctor who is doing a fellowship overseas.) Dr. Lee has sought approval because of his need to inoculate human stem cells in a cerebral ischemia animal protocol. He had been working with stem cells isolated from human adipose tissue obtained from Dr. Katz. The IBC needs to be certain that Dr. Katz is sure that people to whom he gives human tissues have IBC approval or that they get approval prior to initiating work. Dr. Hammarskjöld said she would write to Dr. Katz to explain the importance of telling people who use his adipose tissue that they need IBC approval. Dr. Leonard wanted the committee to talk about how to respond to this problem and also how do we handle absent investigators that have ongoing biohazardous research in their laboratories during their absence. Right now, investigators only sporadically inform the IBC office if they're going on sabbatical or will be absent from UVA for an extended period of time. There's less assurance of proper procedures occurring in approved laboratories when the PI is absent. Currently the IBC does not have any procedures in place to handle the matter of investigator absence. We need to produce a policy about absent PIs.

Dr. Hammarskjöld then asked the committee about the protocols.

- A. ROBERT KADNER uses *Salmonella typhimurium*. Leonard and Gratz visited him on 9/1/04 and his protocol was tabled until we confirmed that he was properly separating garbage. Jean Gratz who emailed me that he is compliant visited him again. Dr. Leonard said that all the outstanding issues appeared to have been corrected. He was approved unanimously and given protocol #200-04.
- B. SANFORD FELDMAN (108-00) uses *Salmonella typhimurium*, *S. enteritidis*, *Shigella flexneri*, *Bartonella bacilliformis*, *Campylobacter jejuni*, *Bacillus anthracis* Sterne strain, methicillin resistant *Staphylococcus aureus*, replication deficient (delta E1a delta E) adenovirus type 5 containing the guinea pig adenovirus hexon gene, human embryonic kidney 293 cells, MCF-7 human breast cancer cells, human tissues and human serum. He has moved his lab to the MR5 building and needed a lab visit. Leonard and Gratz visited him on 9/30/04. He had to get a transfer box, but has since gotten it. He was approved unanimously.
- C. IAN J. SAREMBOCK (032-96) was last visited 7/24/02. He was last approved for primary cells derived from human tissues, human blood and plasma. He's asked to add a lentiviral delivered anti-HDGF shRNA and human cell lines such as HEK 293 cells. He needs to have a lab visit due to his addition of viruses. Dr. Hammarskjöld asked to be included on the visit.

Marjorie Maxey had to leave at this time.

Dr. Leonard then gave us an update on the next registration request. Vaughn hopes to send out trial URL's next Friday. He may ask us to have another meeting to look at the registration or he'll email everyone the information.

Our next meeting will be Monday, November 15 at 5:00 p.m.

## UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

November 15, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Sanford Feldman, Susan Kiley, Tom Leonard, and Marjorie Maxey. Since several people have to leave early, Dr. Hammarskjöld started with the following:

Protocols with new lab visits:

- A. SHAYN PEIRCE-COTTLER uses human adipose derived stromal cells from Katz's lab, and this is a new lab. Dr. Leonard and Jean Gratz visited her on 10/25/04. She had a few items to do, but got them cleared up quickly and Jean Gratz checked her out again and everything was in order. Dr. Leonard recommended her approval. The committee voted unanimously to approve this protocol and it was given protocol number 201-04.
- B. AMY BOUTON (074-99) uses VSV pseudotyped virus, the Ebola virus-like particles (VLPs), Ebola GP cDNA, retroviral-based vectors, Yersinia pseudotuberculosis, Yersinia enterocolitica and tissue culture cells of human origin. Dr. Leonard and Jean Gratz found that she needed to have the sign-up page in her lab manual updated when they visited her 10/25/04. Gloria Bowers said that this had been done. Dr. Leonard then recommended her lab be approved. The committee voted unanimously to approve this protocol.
- C. DAVID W. MULINS uses Vaccinia viruses expressing ovalbumin protein or ovalbumin-derived peptide sequences, T cells and tumor lines of human origin. He has a new lab and was visited 10/27/04 by Drs. Hammarskjöld and Jean Gratz. Jean Gratz did not find anything out of order with the lab. He shares his space with Dr. Bullock and it's in very good shape. Dr. Hammarskjöld spoke to him about his work and recommended him for approval. The committee voted unanimously to approve his protocol and he was given protocol number 202-04.
- D. TOM STURGILL (053-98) has been using human cell lines and storing recombinant Vaccinia virus. Dr. Leonard and Jean Gratz visited him 11/15/04. He had several issues that needed to be addressed before he could be approved. His lab members were washing their lab coats at home, which is against OSHA regulations. They had been sending them out, but can no longer put this charge on their grants and have not as yet found an alternative. Gloria spoke to the Grants administrator in Pharmacology and she understands the problem and will take it up with the chairman when he returns from a trip. The freezer where they were storing the Vaccinia was in a public hallway, but not locked. They needed signs and stickers which they were given and told how to use. Their lab manual needed more explanation on their signature page. They need to have Hepatitis B as well as Vaccinia tracked. They are using a Bunsen burner in the hood and Dr. Leonard suggested that they replace it with a touch plate. Dr. Sturgill's response was very unusual. He was hostile to all of the



suggestions. Dr. Leonard suggested that they not be approved until all of their issues are resolved.

- E. JOHN K. HAYES uses shiga toxin and Ricin toxin with Dr. Obrig. He has a new protocol and was visited by Dr. Leonard and Jean Gratz on 11/15/04. He had been working on his lab with Jean Gratz and as a result everything was in order when he did his official lab visit. Dr. Leonard recommended his approval. The committee voted unanimously approved this protocol and it was given protocol number 203-04.

New protocols:

- A. NORBERT LEITINGER uses cells isolated from human tissues. He needs a lab visit.
- B. ANINDYA DUTTA uses human papilloma virus, Kaposi's Sarcoma Associated Herpes virus, human cell lines, adenovirus, retrovirus, human tissues, and baculovirus. The committee would like a list of the types of human cell lines. The committee did not find enough information in the write up. Dr. Hammarskjöld asked to go on this lab visit.
- C. MARIO GEYSEN uses human sera. Dr. Leonard said that Dr. Geysen wants to be approved quickly. He needs a lab visit.
- D. COSTI D. SIFRI uses bacteria and is a new researcher at UVa. He needs a lab visit.
- E. PAUL S. HOFFMAN uses bacteria and needs a lab visit.

Protocols to renew:

- A. MICHAEL J. WEBER (022-96) was last visited 6/17/03. His renewal doesn't indicate if he's still using polytrophic retroviruses. The committee conditionally approved him. They'd like to know about the retroviruses first.
- B. MARTIN A. SCHWARTZ (150-03) was approved last May for human umbilical vein endothelial cells and human cell lines since he said he had a change in his protocol. However he had wanted to retain the recombinant DNA and replication defective retroviral vectors and adenovirus, but had not indicated it. So he would like to add it back to his protocol. He was last visited 4/30/03 for the recombinant DNA and replication defective retroviral vectors and adenovirus. The committee would like to do another lab visit and ask about the retroviral work (ecotropic or amphotropic?).
- C. LARISA V. GUBAREVA (072-98) was last visited 9/27/01. She's due for her 3-year-a-lab visit.
- D. JOANNA B. GOLDBERG (059-98) was last visited 5/13/02. Her protocol remained the same. She was unanimously approved for renewal.
- E. J.T. PARSONS (070-98) was last visited 04/03/03. He wants to add human cells lines to his protocol. He was unanimously approved for renewal.
- F. BARBARA MANN (900-04) has experiments she wants approved for the BSL3. We needed to change Dr. Mann's BSL3 approval number, which she does alone to separate it from her BSL2 work, which she does with Dr. Petri.

We will rewrite her BSL3 approval letter in which we change the number. The committee wants to hold off approving her BSL3 work, which she describes in her October 21, 2004 letter until the CDC approves it.

**New Business:**

- A. Dr. Feldman had to leave before the meeting was over, but he wanted to tell the committee about setting up a trip to Fort Detrick in order to show the workmen in Facilities Management how to work with BSL3 safely. He said that one of the interesting rules for entering Ft. Detrick was that only people who are citizens could go. People with only green cards would be excluded although they only ask for 2 pieces of ID.
- B. Dr. Leonard referred the committee to the newly posted Biotoxin Inactivation guidelines on the website. If anyone has any corrections or questions about them, they should advise him directly.
- C. Dr. Leonard also told the committee that if he did not hear any further comments about the updated Biosafety Manual, which had been sent to everyone by email, he would post the new manual at the next meeting.
- D. The new online registration should be in effect January 3, 2005. He hoped to have a new version for the December IBC meeting. Dr. Hammarskjöld asked that the letter asking PIs to renew explain that the IBC needs to approve retrovirus vectors since it's important to know what people are putting into human cells. Dr. Leonard said that we could do this in either the letter or elicit this information in the actual application.
- E. Tom Leonard told the committee about the fire in Colleen McNamara's biosafety cabinet caused by a touch plate. Jean Gratz in his office went to the fire and gave the lab a list of items that needed to be done.
- F. It was too difficult to plan a new lab meeting since some people had to leave. It was decided to do it by email.

## UVA INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

December 9, 2004

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Sanford Feldman, Susan Kiley, Thomas Leonard, and Marjorie Maxey. Vaughn Kowahl from the Office of Environmental Health and Safety attended to speak to the committee about the new registration process.

### 1) Protocols with new lab visits:

- A. MARTIN SCHWARTZ (150-03) visited 11/24/04 by Drs. Kiley and Hammarskjöld and Gratz. Dr. Hammarskjöld explained that the lab was in good shape. She was concerned that he makes changes to the lab manual to make it clear to anyone in the lab that only ecotropic receptors should be used. He made this change to his lab manual. His protocol was approved unanimously.
- B. PAUL HOFFMAN visited 11/30/04 by Drs Leonard and Mann and Jean Gratz. He has shown Barbara Mann the changes to his signature page, his signs and his transport box. All of these items now comply. His protocol was approved unanimously and given protocol number 204-04.
- C. NORBERT LEITTINGER visited 11/30/04 by Dr. Leonard and Jean Gratz. He needed additional changes to his signatures, different chairs or covers for the chairs and signs. He's done all of these requirements. His protocol was approved unanimously and given protocol number 205-04.
- D. ANINDYA DUTTA visited 11/30/04 by Drs. Hammarskjöld and Leonard and Jean Gratz. The auditor originally brought this lab to our attention. They are a very large lab and some of the items they have for approval such as the human Kaposi sarcoma Associated Herpes virus don't need approval since they are working with less than 2/3 of the genome. The visit was useful in that they were educated. They needed to have signs and labels, which they got and are now using. They had issues with radioactivity and Jean Gratz has suggested that OEHS's Radioactivity people look in on them. Since they have addressed all their IBC issues, they were approved unanimously and given protocol number 206-04. The committee suggested that we continue to monitor them.
- E. LARISA GUBAREVA (072-98) visited 12/3/04 by Jean Gratz. This was a 3-year visit. She was in excellent shape. She was approved unanimously.
- F. MARIO GEYSEN visited 12/8/04 by Dr. Mann and Jean Gratz. Dr. Mann sent a note saying that this lab was in very good shape and recommending that they be approved. Tom Leonard said that Jean Gratz had also told him that this lab was in good shape. They were unanimously approved and given protocol number 207-04.

### 2) New protocol:

- A. MILTON BROWN, from Chemistry, has been working with established human cancer cell lines, but with the changes in the IBC protocol with human cell lines, they have had to register. He needs to have a lab visit.
- B. RICHARD J. SANTEN from Medicine, has been working with human MCF-7 breast cancer cell lines. He needs to have a lab visit.
- C. JULIE SANDO from Anesthesiology and wants to work with human embryo kidney (HEK) cell lines. She needs to have a lab visit.

3) Protocols to renew:

- A. W. MICHAEL SCHELD (041-97) visited 1/6/03. He uses enteropathogenic *E. coli*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *S. Aureus*, *S. anginosus*, *S. intermedius*, *Listeria monocytogenes*, and *Bacteroides fragilis*. He wants to renew with no changes. His present renewal was approved unanimously. Dr. Feldman indicated that he had asked to have some Anthrax, stern strain. We may want to ask if he wants to work with this.
- B. ADAM KATZ (140-02) visited 9/4/02. He uses human tissue. He has also agreed to screen people to whom he gives cells. He's asking that they show him their IBC approval. He wants to renew with no changes. He was approved unanimously.
- C. JOHN C. LAWRENCE (125-01) visited 9/26/01. He uses replication deficient adenovirus and cell lines. He wants to renew with no changes. He needs a 3-year lab visit.
- D. KENNETH BRAYMAN (157-03) visited 6/6/03. He uses human pancreatic cells isolated from cadavers, adenoviral vectors and cell lines. He wants to add fat stem cells to his protocol. He was approved unanimously.
- E. JOHN HERR (036-98) visited 2/17/04 wants to add uropathogenic *Escherichia coli*, *Staphylococcus aureus*, group D, *streptococcus*, *T-Mycoplasma* and *Chlamydia traachomatis* to his protocol which includes human, non-human primate tissue/fluids and growing *E. coli* in excess of 10 liters. Since he's starting to use very different material, the committee wants to give him a lab visit.
- F. BARBARA MANN has received her approval to begin her BSL3 work from CDC. We were waiting for this approval before giving her the final approval to begin her BSL3 work at the last IBC meeting. She was approved unanimously.

4) NEW BUSINESS:

- A. Dr. Hammar skjöld told the committee about an email that Dave Hudson received from NIH, OBA that said that there would be site visits in the coming year.
- B. Both Drs. Feldman and Leonard expressed some frustration about MR6. Richard Allen who is the project manager and has not been very receptive to criticisms about contractors who had worked on MR5. Particularly, Atlantic Controls who set up the air system which has had air balancing problems that don't appear to be getting better. Since MR6 will have BSL3, the air balance is particularly important. Dr. Feldman informed representatives of the Dean's

Office in the School of Medicine to make certain this concern was known to the appropriate interested parties. It is not clear at this time what steps will be taken to ensure a reliable air-handling control system will be installed in MR6. This is just one instance of the problems that keep occurring. Dr.

Hammarskjöld said that this is similar to the problems she had and was unable to resolve in getting any information from Richard Allen, the senior project manager of Facilities Planning and Construction.

- C. Vaughn Kowahl showed the committee the new IBC registration. The first change that the committee wanted was to have the committee filter any additions to the various material lists. Right now, if someone fills out the "other", whatever is added to "other" becomes part of the list. Since people are not always accurate, the committee wants it to administratively go to Gloria Bowers who will then check with the committee before adding it to the appropriate list. This system allows the IBC to give out multiple numbers for the same PI. The committee suggested that the vaccine prompt be very complete to address institutional and PI liability. This is also addressed in the new Biosafety Manual and discussed during Bloodborne Pathogen Training. There will be some new text on toxins. The committee decided that there's no need to have a title of the experiment since the material under specific conditions is being approved and not particular experiments. Vaughn said that he could divide up the list any way the committee asks.
- D. Future meeting date. Since many people had to leave, it was decided to email everyone about the next meeting.

MINUTES  
INSTITUTIONAL BIOSAFETY MEETING  
January 18, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Tom Leonard, Susan Kiley, Barbara Mann and Marjorie Maxey.

The meeting opened with a renew of the protocols with new lab visits:

- A. JULIE SANDO was visited 1/6/04 by Jean Gratz and Tom Leonard. Her lab was in very good shape. She asked and was preliminarily approved by email. The committee again approved her protocol.
- B. JOHN C. LAWRENCE, JR. was visited by Jean Gratz and Tom Leonard on 1/6/04. He needs several items. He needs to clean up his waste; training, satisfactory cleaning arrangements for lab coats; and to replace a chair in their tissue culture room. Despite several emails, no one has advised Gloria that these items have been resolved. His protocol was tabled.
- C. It was agreed that if there were outstanding items with protocols, we would wait two months, and then send a letter from the committee in which we'll advise the PI that he cannot work with the materials he requested since he has not resolved open issues with the committee.

Protocols with current lab visits:

- A. AMY BOUTON (074-99) was last visited 10/25/04. She has used *Yersinia enterocolitica*, *Yersinia pseudotuberculosis*, retroviral vectors for infection of mammalian cells, Ebola virus-like particles (VLPs), the use of cDNA encoding the glycoprotein (GP) of Ebola virus, the use of Vesicular Stomatitis Virus (VSV) Indiana strain pseudotype particles and cell lines of human origin. Her online registration was incomplete. Gloria will contact Dr. Bouton about completing her form.
- B. DAVID JONES (149-03) was last visited 3/31/03. He has used recombinant DNA, adenovirus and retrovirus. He was approved since he has no changes.
- C. AMY TUCKER (118-01) was last visited 6/3/04. She has used adenovirus, human derived monocytes and macrophages. She's changing the description to blood and blood components. She has not completed her online registration and needs to be notified to do so.
- D. ERIK HEWLETT (021-00) was last visited 9/3/03. He uses toxins from *Bacillus anthracis* lethal factor (LF), edema factor (EF) and protective antigen (A); *Bordetella pertussis*; adenylate cyclase toxin (ACT), Pertussis toxin (PT), *Bacillus anthracis* (Sterne strain), human cell lines and human blood products. He wants to add cholera toxin. He is currently on sabbatical. Everyone agreed that he would be approved as soon as he completed his registration online.
- E. At first it was suggested that Gloria Bowers could check to see that new online registrations were complete and then just approve those protocols that had current lab visits, expiration dates in 2005, and no changes to the protocols. However Dr. Hammarskjöld and Dr. Feldman suggested that the

narratives needed some expertise to approve. So although this may restrict the ACUC approvals, everyone agreed that the Chairman could provisionally approve that the registration is complete and proper. This will apply to those PIs who may currently be approved by the IBC, but who need to pursue their ACUC protocol and need to be approved administratively online. Dr. Hammar skjöld will look over the registration forms they submit online and provisionally approve them. Then Gloria Bowers will approve them online. If there are any changes, then the protocol goes to the full committee.

- F. BENJAMIN GASTON (076-99) was last visited 1/20/03. He was approved for human tissues, human rhinovirus and HRV serotype 16. He needs a lab visit since he's changing his protocol.

Protocols with lab visits that expire this year or earlier:

- A. GARY BALIAN (130-02) was last visited 6/4/02. He uses adenoviruses, *Staphylococcus aureus*, cell lines, human bone marrow cells, adeno-associated viruses, and retroviruses. He needs more detail in his description and he should tell us what is in his vectors.
- B. DONGFENG PAN (077-99) was last visited 1/7/02. He uses recombinant DNA or RNA. He was last approved for recombinant adenovirus vectors. Everyone thought that he used to transfect human tumor cell lines.
- C. YOUNG HAHN (077-00) was last visited 12/19/02. She uses Vaccinia, Sindbis, human blood and recombinant DNA. She's adding cell lines and Hepatitis C. She needs a lab visit.
- D. DOUGLAS BAYLIS (087-99) was last visited 11/20/02. He uses replication deficient adenovirus. He needs to have a lab visit.
- E. THOMAS BRACIALE (018-99) was last visited 10/3/02. He has used Sindbis virus, Influenza (type A and B), RSV, Vaccinia, and recombinant DNA. He's registered for Diphtheria toxin, pertussis and staphylococcal enterotoxins. He needs a lab visit.

New Business:

- A. The new IBC online registration is live. There will be some confusion, but hopefully, we can work through the delays.
- B. The committee discussed IBC training and the new lab manual. Right now the lab visit every three years is compulsory. However, there are more changes such as the new shipping rules for which there is now a class by Jean Gratz. The easiest way to keep everyone current is to require anyone who needs to do OSHA to do the OEHS class annually. Everyone agreed that the training should be compulsory for anyone who needs to do the OSHA training. Also, part of the lab visit will include a requirement to have the new lab manual as part of the lab visit.
- C. PIs only need to tell the IBC that they are no longer using their BSL2 or higher material. There is no decommissioning. It is done by the PI.
- D. The next meeting will be on Monday, February 7 at 5:00 p.m.

**MINUTES**  
**INSTITUTIONAL BIOSAFETY MEETING**  
**February 7, 2005**

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Tom Leonard, Susan Kiley, and Marjorie Maxey.

**1) Protocols with new lab visits:**

- A. DOUGLAS BAYLISS (087-99) was visited 1/20/05 by Leonard and Gratz. He has done his new application online. He fulfilled any open items on his lab visit and then he received a provisional approval by email. He was unanimously approved at our meeting.**
- B. COSTI SIFRI was visited 1/20/05 by Leonard, Mann and Gratz. He has done his new application online and completed all of his open items except for his training, which he is due to complete. Right now he has had some conflicts with completing it, however, Dr. Leonard felt that he could still recommend his protocol be approved. He was unanimously approved.**
- C. YOUNG-SHIN HAHN (077-99) was visited 1/31/05 by Kiley and Gratz. She has done her new application online and her new lab manual. Her lab was excellent. Right now she is not working with Hepatitis C and we should ask her to tell us when she starts work. She was approved unanimously.**
- D. THOMAS BRACIALE (018-99) was last visited 2/7/05 by Tom Leonard. He has done his new application online and completed the new lab manual. Sections which document Hepatitis B vaccination status are in need of revision, and certain sharps disposal practices may need to be modified. Jean Gratz will revisit the laboratory next week to provide follow-up assessment consultation regarding these issues. They currently have animals in their BSL2 lab (which is just one room). The animals are all in a hood. They had been using 100% bleach, but were advised that 10% is sufficient as long as it's kept fresh. We will ask them to notify us when they resume Sindbis work. There was a discussion about the utility of asking people to notify the committee when they begin to use something when they have it on their protocol. Several people felt that the registration might have materials that are only stored and that the committee should be aware of what may be actively used. It was decided to discuss this at the next meeting. We need to find out from the Braciale lab what hazards are associated with ectromelia they are using (i.e.. human, animal, etc). They were unanimously approved for everything except the ectromelia. Dr. Hammarskjöld will look at it when the Braciale lab explains what they are doing with it and if it is infectious. Additionally, the committee discussed the status of vaccinia vaccination among laboratory staff. All staff had documented that they had been vaccinated or declined the offer of vaccination. Dr. Leonard volunteered to present current vaccinia vaccination guidelines to Dr. Braciale, along with a copy of the UVA Policy on Vaccinia Vaccination.**



- E. JOHN C. LAWRENCE was last visited 1/6/05. He has submitted his lab manual, but needs to complete his online registration. His protocol is tabled until he has done his online registration.

2) The following protocols have current lab visits and current approval, which needed to be updated online after review and approval by Dr Hammarskjöld:

- A. SHAYN PEIRCE-COTTLER (201-04) was last approved 11/15/04
- B. JULIEANNE SANDO (208-05) was last approved 1/5/05.
- C. THERESE GUISE (189-04) was last approved 6/10/04.
- D. JOHN CHIRGWIN (190-04) was last approved 6/10/04
- E. KENNETH BRAYMAN (157-03)) was last approved 12/9/04.
- F. BARBARA MANN (002-96) was last approved 11/15/04.

3) Protocols with lab visits that expire this year or earlier:

- A. JUN JULIUS ZHU (135-02) was last visited 2/22/02. He needs a new lab visit.
- B. MANI MAHADEVAN (141-02) was last visited 9/25/02. He needs a new lab visit.

4) New protocols:

- A. MARIA MONTEAGUDO requested more information. This is not a PI, but is a lab tech. Susan Kiley is familiar with the lab and will talk to the PI and get the correct information.
- B. BETTINA WINCKLER needs to modify her protocol to describe her work with HEK 293 cells.

5) Protocols with changes or questions:

- A. ERIK HEWLETT (021-00) was last visited 9/3/04. He has just completed his protocol online. We need to find out if they are just using the toxin or are using the bacteria and making the toxins. If they are just using the toxin, they need to put the toxin under toxin online. The committee unanimously approved the use of the toxin.
- B. JOANNA GOLDBERG (059-98) was last visited 5/13/02. She has added *Klebisella pneumoniae* and *Salmonella typhi*. Her changes were unanimously approved.
- C. RONALD TAYLOR (049-98) was last visited 8/5/04. He is adding Anthrax Protective Antigen (APA) and Anthrax Lethal Factor (LF) to his protocol. It is unclear whether these toxins need to be controlled by the IBC. Dr. Hammarskjöld will contact the OBA about this.
- D. JAMES ROCHE (111-00) was last visited 6/3/04. He is adding blood and cell lines to his protocol. He had these items on his protocol in 2003, but dropped them. He wants to add them again. He needs to give us a description of his human work. There was some confusion since he is on sabbatical and working with Obrig, but also keeping his own protocol and working with Guerrant.

- E. MARTY MAYO (119-01) was last visited 3/31/03. He is adding cell lines to his protocol. He needs to name the cell lines he's using and if they are established cell lines. He was approved unanimously.
- F. SCOTT VANDER POL (169-04) was last visited 2/4/05. Dr. Hammarskjöld felt that we had previously overlooked the fact that he is putting oncogenes into amphotropic cells. She feels that we should do another lab visit to be sure that his procedures are safe. There was a discussion about what an enhanced BL2 would be needed for this protocol. Also, what factors would make this more safe, i.e. how often it is done, who else is in the room while it is done, what happens to spills when this is done, etc. It was decided to do a lab visit and to do some research into the amphotropic retroviruses he uses. His proposal was approved with the exception of the amphotropic retroviruses which are subject to further evaluation.
- G. CATO T. LAURENCIN (165-03) was last visited 10/30/03. He has just completed his protocol online. He was unanimously approved.

#### 4) NEW BUSINESS:

- A. Discuss the outbreak of *Francisella tularensis*. The committee discussed the Boston outbreak and the consequences of it. The Chairman of Infectious Disease who had just received a Program Project Grant from NIH had to step down as Chairman. The announcement of the outbreak came after the Boston Planning Board approved the University for a BSL3 and BSL4 facility. The committee agreed that it would be prudent to discuss this matter with Dr. Mann upon her return to assess whether any policy or procedural modifications should be considered.
- B. Discuss the new online procedure. We will be sending more protocols out to everyone to read before the meetings to take advantage of the new online forms. During Dr. Hammarskjöld's trip to meetings, Dr. Susan Kiley will take over approving the protocols for ACUC.
- C. New meeting will be March 14, 2005 at 5:00 p.m. in room 7100 in Jordan Hall.

## MINUTES

March 14, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Ron Herzig, Tom Leonard, Susan Kiley, and Marjorie Maxey.

The meeting opened with a discussion of protocols with new lab visits:

- A. BRETT BLACKMAN (147-03) was visited on 2/28/05 by Leonard and Gratz and again 3/14/05 by Leonard. Dr. Blackman missed the first visit that was scheduled, but he was prepared for the second visit and his lab personnel are going to biosafety training prior to the follow-up visit. He was recommended for approval. He was approved unanimously.
- B. JULIUS ZHU(135-02) was visited 2/28/05 by Leonard and Gratz. He doesn't have HEK cells listed under human material and he needs to give a better description of his work. He needs to declare that he doesn't have any recombinant work, but his descriptions indicate that he does. He needs to give a better description of what he's doing.
- C. JOHN HERR (036-98) was visited 2/28/05 by Leonard and Gratz. He was approved by email on 2/28/05. He is doing extensive research in sperm, reproduction, etc. and as a result uses human material, bacteria, and recombinant DNA work in several locations. It is suggested that they remove the recombinant portion of the protocol and have it approved now. Then add it after it's complete so that we can get most of it approved. Everything was unanimously approved on their protocol except for their recombinant DNA work, which we have requested that they rewrite.
- D. GEORGE RODEHEAVER (020-98) was visited 3/14/05 by Leonard. Dr. Rodeheaver had been visited by Gloria Bowers and Jean Gratz earlier in the month. He did not have any open items. He still has one person to attend class, but other than that, he's in very good shape. He was recommended for approval. He was unanimously approved.
- E. GARY BALIAN (096-99) was visited 3/2/05 by Leonard and Gratz. He was approved by email on 3/3/05. Dr. Leonard said that he had fulfilled everything under his lab visit and that almost everyone had done their class. However, Dr. Hammarskjöld asked what kind of envelope he's using. No one could find the answer in the protocol, so we'll ask him to add it to his protocol.
- F. JIM CASANOVA (098-99) was visited 2/28/05 by Leonard and Gratz. He had some items outstanding on his lab visit. Again, it was asked which cell lines he uses, which genes he's expressing; which envelopes he's using and if he's using amphotropic or ecotropic expression. He was put on hold until we clear up these, and other matters identified during the laboratory visit, including cloth-covered chairs, use of bunsen-burner with a BSC, signage, etc.

- G. MANI S. MAHADEVAN was visited 3/2/05 by Leonard and Gratz. Dr. Mahadevan had some outstanding items on the lab visits, but hasn't gotten back to us about them. He also needs to tell us the cell lines he's using, which genes he's expressing, and which envelops he's using and if he's using amphotropic or ecotropic cells. He too was put on hold until this is cleared up.
- H. BETTINA WINCKLER (new protocol) was visited 3/2/05 by Leonard, Gratz and Ernst. Dr. Ernst told everyone about the problem Dr. Winckler had when she searched for the lab manual template and found the old template. Dr. Leonard explained that he had discovered that it is possible to acquire an older version of the biosafety manual if one conducted a UVA-specific Google search using the term "biosafety manual". Dr. Leonard consulted with Vaughn Kowahl, who will incorporate revision dates into the document title in order to minimize future confusion. Vaughn indicated that there may be no way to scrub older versions of the manual from cyberspace for technical reasons. She needs to have her lab manual re done as a result. She also needs to add HEK Cells and 293 cells to her protocol
- I. JOHN LAWRENCE was visited 1/6/05 and again 1/31/05. He had complied on everything on his lab visit, but had to do his online registration. He has done that, however it is inadequate. It does not include enough information.

The committee then looked at protocols with current lab visits and current approval whose approvals were updated online after approved by Drs. Hammarskjöld or Kiley. No one had any objections to any of their protocols and we will remind them to renew at the appropriate time.

- A. TOM G. OBRIG was last visited 1/29/03 and approved 8/3/04.
- B. RAGHU MIRMIRA (131-02) was last visited 8/30/02 and approved 7/15/04
- C. JOHN K. HAYES (203-04) was last visited 11/15/04 and approved 11/15/04.
- D. ZHIYI ZUO (183-04) lab was visited 3/24/04 and approved 5/5/04.
- E. G. PAUL MALTHERNE (083-99) was visited 7/23/03 and approved 9/13/04.
- F. MASUMI ETO (197-04) was visited 8/10/04 and approved 8/19/04. He has a protocol co-signed by Dr. Brautigan.
- G. SHYRE-TE JU (191-04) was last visited 6/10/04 and approved 6/10/04.

The committee continued to review the renewal protocols with lab visits that expire this year or earlier and new protocols. All of these protocols need a lab visit, but everyone was asked if they have any comments about the protocols at this time. We will ask the PIs to update the protocols if need be. Everyone who hasn't read these protocols should read them and give Gloria Bowers any changes.

- A. R. ARIEL GOMEZ (084-99) lab was last visited 6/1/99. Everyone believes that Dr. Gomez does recombinant DNA work and we will ask him before we do his lab visit.
- B. JAY BROWN (057-98) lab was visited 1/29/01.
- C. KEVIN HAZEN (017-97) lab was visited 11/25/02. We need to have him correct his lists of material. He's put BSL1 in parenthesis and it is not

applicable. There is some difficulty in determining why someone put BSL1 on some BSL2 agents.

- D. REID ADAMS (114-00) lab was visited 9/11/2000. Dr. Adams needs to give us a list of what he is putting into his vectors.
- E. MARK STOLER (061-98) lab was visited 5/19/98. He doesn't identify his vectors.
- F. LAUREL RICE (058-98) lab was visited 12/12/01.
- G. KENNETH PFISTER (120-01) lab was visited 3/29/01.
- H. JOHN CASTLE (143-01) lab was visited 9/25/02. John Castle needs to have OBA approval to clone toxins as well as IBC approval. Dr. Leonard reported that he spoke with Castle and they say they are not currently doing the work, but they may want to pursue it in the future. It was asked if they have possession of the cloned toxin and if they do, should they get OBA approval to store it? We can ask them to remove the cloned toxin and then approve the protocol and they can get approval for the cloned toxin at a later date. Meanwhile we should contact OBA to see if storage needs to have their approval. They'll need a lab visit in any case.
- I. KAREN FAIRCHILD new PI.
- J. MILAGROS HUERTA new PI.
- K. JEFFREY WIMSATT proposes to work with rabies, which appear to be in storage. He'll need to do the shipping class and also needs to explain how he is storing the materials.
- L. GAIL WERTZ new PI. Dr. Wertz is not yet in the University. She's in Pathology. She uses RSV and genes, which are manipulated. She's trying to modify the tropisms of RSV to direct it to go to other organs. Everyone needs to read this. It was suggested that an outsider read the protocol and advise us on it. She is moving to UVA from the University of Alabama with her husband Andrew Ball. Dr. Hammarskjöld is to call OBA and get recommendations of who might be good to read the protocol. Some of the work may need to be done in a BSL3. Everyone agreed we should seek expert another opinion regarding the appropriateness of conducting the proposed work at BSL2.
- M. ISA HUSSAINI (186-04) was visited 6/2/04. He needs to tell us what genes he is cloning into virus vectors.

The committee then looked at the protocols of people who are renewing their approvals. The committee has until 3/14/05 to read these protocols and advise if there are any changes needed.

- A. MARGO ROBERTS (090-99) lab was visited 9/8/03.
- B. XIN-DE (ROBERT) SONG (168-04) lab was visited 2/5/04.
- C. ROY OGLE (172-04) lab was visited 2/11/04 and last approved 4/1/04. Dr. Kiley approved their protocol for ACUC until 4/1/05, but they'd like to have their protocol approved for the next year since they don't anticipate any changes.
- D. MICHAEL WEBER (022-96) lab was visited 6/17/03.
- E. SANFORD FELDMAN (108-00) was visited 9/30/04.

5) Protocols with changes:

A. BARBARA MANN (002-06) lab was visited 9/13/04. Dr. Mann is asking to add human sputum and saliva to her protocol which already included a range of human materials. Her changes were approved unanimously. She will be asked to be sure to update her lab manual to include this material.

6) Other business:

- A. Discuss a policy on gene transfer vectors, for example Dr. Scott Vande Pol visited 2/3/04. He's occasionally using human amphotropic vectors. Dr. Hammar skjöld met with Dr. Vande Pol and feels that his work could progress with strict BSL2 with extra care such as restricting use of the room when this work is being done. Also, training everyone who will do this work about the problems. He'll need to modify his lab manual to reflect this.
- B. Discuss how IBC wants to review the ACUC or animals. At a recent ACUC meeting, some members inquired with Dr. Leonard about the extent to which the IBC evaluates animal experimentation involving biological agents. It was asked at the ACUC if the IBC wants to know about animals. Several members said that we should ask for a short description about their animal work and find out if the work is in the animal facility or a satellite lab. The matter was not fully resolved however Dr. Leonard offered to draft a question that would eventually be incorporated into the registration narrative section.
- C. Delinquent PIs and PIs who are not responding to our requests to do protocols. For example Fox, Sturgill, Lawrence. This may be cleared up later since we may get recommended changes as a result of the audit process. It is proposed that we should enact her recommendation about getting people to renew as follows: First, they'll be reminded by Gloria Bowers. Next a letter will go to the PI from the IBC chairman. Next a letter will go to the PI's chairman from the IBC chair. Finally, David Hudson/Ariel Gomez will be asked to write a letter.
- D. Results of the UVA Internal Biosafety Audit. Karen Eldridge will be releasing an audit and there may be some changes in IBC getting more control over PIs. Dr. Leonard stated that a preliminary audit report indicated the more frequent inspections of laboratory areas is recommended to enhance detection of investigators who may be operating without appropriate IBC registration. Additionally, the Office of Sponsored Projects will modify their procedures to alert OEHS of investigators who intend to pursue work with a range of hazardous materials, including biological agents. These steps should minimize unregistered investigators.
- E. The date for the next meeting is Tuesday, 4/12/05.

## MINUTES

April 12, 2005

Barbara Mann, acting Chair, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Tom Leonard, Susan Kiley, and Marjorie Maxey.

1. The meeting opened with Barbara Mann introducing Kevin Hazen who came to present his views on the containment necessary to safely handle several organisms that he uses, specifically *Aspergillus* sp., *Candida* species, *Stachybotrys chartarum*, *Trichoderma* sp. and *Candida albicans*. Dr. Hazen is the Director of Clinical Microbiology for the UVA Hospital, as well as a professor of pathology. Dr. Leonard then provided some background on the matter and reviewed the information that the committee had been discussing by email, specifically related to *Candida*. He said that the committee had not been able to find direction as to how these organisms should be used in the BMBL, but that there was some information in Canada and Europe where they describe these organisms as BSL2. At the same time, he noted that most references consider *C. albicans* to be an opportunistic pathogen, which does not normally require BSL2 containment. Dr. Hazen was invited to address the committee.

Dr. Hazen said that most fungi are opportunistic, but that none are passed person to person. He told of a person who had ingested a liter of *Candida* and only had a mild stomach discomfort from it. He said that in the past, there were instances in which *Candida* was believed to be BSL2, but that it is in fact BSL1 based on the fact that it is exclusively an opportunistic pathogen, and poses no risk to healthy adult humans. In fact he tells everyone in his lab not to work with fungi if they are sick. He said that he believes that the international agencies in question categorize it as BSL2 in order to “feel good”, but that they give no evidence of their statements from the literature. Although they say there have been 2 lab accidents, he can’t understand how they occurred and they don’t give references. He can only think it may have been injected, but he believes this would happen only with “sloppy techniques”.

Barbara Mann said that there are other opportunistic organisms that are classified as BSL2 such as *Pseudomonas*. Why not simply classify *Candida* the same way? Dr. Hazen responded that *Pseudomonas* is more easily aerosolized and more infectious, but that *Candida* is not infectious when aerosolized. Aerosolized *Aspergillus* can rarely cause infection and that’s with a compromised immune system.

Sanford Feldman commented that it’s easier to make blanket decisions about microorganisms than to consider each individually. Dr. Hazen said that there are times when the implications of the decision should be taken into consideration.

Dr. Leonard asked if we could assume that healthy, adult humans are not at risk from *Candida albicans* and Dr. Hazen said “yes”. He said that we all carry it. There is speculation that if you had antibiotics; *Candida* will blossom when normal bacterial flora

are removed. There are also times when *Candida* causes a localized infections around catheters but if a catheter is being used, it's assumed these are not healthy humans. Addressing other agents used in Dr. Hazen's research, he went on to explain that his group always uses *Aspergillus* in the hood although he believes that it is a BSL1 agent. Any mold that sporulates presents greater risk because of the potential for aerosolization. Dr. Hazen prefers to classify each of the organisms listed as BSL1. He feels that it opens up problems when they are called BSL2 and they aren't true pathogens, or at least not normally a pathogen in most humans.

Dr. Feldman said that we can't classify organisms by "common sense" or on an individual basis; most people will want to back down their safety practices to BSL1 simply for convenience. He also noted that we as a committee have concerns about precedence given that this could result in many PIs requesting review of individual microorganisms where the guidelines are vague. Dr. Mann said that the BMBL is a guideline, but the committee can decide to increase to more stringent practices. Dr. Hazen said that each individual researcher is ultimately responsible for the practices he allows. Dr. Feldman said that he'd prefer to see the practices ratcheted up rather than down. Then Dr. Hazen said that guidelines might need to be modified for the venue they serve. Dr. Leonard said that NIH assumes that everyone should follow the guidance of BMBL and that most institutions just make the BMBL their policy. The BMBL indicates that *Stachybotrys* is BSL2. Dr. Hazen said that he thinks that *Aspergillus fumigatus* is considered the most virulent among the *Aspergillus* species he works with. When asked how he'd rank the risk of *Candida albicans* in comparison to *Aspergillus*, Dr. Hazen indicated that he would apply a 4 and 10 out of 100, respectively. Dr. Leonard asked if a healthy adult could get *Aspergillosis* and Dr. Hazen replied that there are allergic respiratory reactions in people, but these people usually have a hypersensitive immune system.

Dr. Mann asked if there were any other questions and there were none. She thanked Dr. Hazen for coming and said that the committee would need to talk about this and he'd be notified as to the decision. Dr. Hazen thanked the committee and left.

Dr. Mann asked why the committee couldn't just have *Candida albicans* as a BSL1 and *Aspergillus*, *Stachybotrys chartarum* and *Trichoderma*, as BSL2? Although Dr. Hazen was interested in maintaining *Aspergillus* and *Trichoderma* at BSL1, the committee noted that Dr. Hazen stated that he routinely employs BSL2 practices for these agents. Dr. Leonard said that at times this committee as a group puts organisms into BSL2, which may not be there in the BMBL due to other considerations. Everyone appeared to agree that Kevin Hazen had made a good case that *Candida albicans* be classified as BSL1. Dr. Susan Kiley moved that we make *Candida albicans* and *Candida* sp BSL1 and that *Aspergillus* sp, *Trichophyton* sp., and *Stachybotrys chartarum* remain BSL2. This motion passed unanimously.

2. Protocols from the last meeting of people who have current lab visits but the committee needed more time to review the protocols:



- A. MARGO ROBERTS (090-99) was last visited 9/8/03. Dr. Leonard could not find that Dr. Roberts' lab had attended the blood borne pathogens class, but they were seen there, but not on the OEHS list. Ms. Bowers will ask the Micro Department to be sure to tell research staff signs in for the class to be sure to receive credit. This protocol was approved unanimously.
- B. XIN-DE (ROBERT) SONG (168-04) was last visited 2/5/04. He has revised his protocol since it was sent to the committee. It was asked if he's actually in with Dr. Santen's group. He was approved unanimously.
- C. ROY OGLE (172-04) was last visited 2/11/04 does not have any changes. Dr. Mann suggested that we may want to do a spot check on this lab since it has had sloppy housekeeping. He was approved unanimously.
- D. MICHAEL WEBER (022-96) WAS LAST VISITED 6/17/03. There are numerous problems with the protocol as it is. It's unclear what organism they are talking about in different questions, specifically G, H and there is no J although they do have animal studies. They also failed to declare any biotoxins although they make reference to their use. The protocol was tabled pending corrections. Dr. Leonard volunteered himself and Jean Gratz to help people with their protocols. It was also suggested that we have a workshop on protocols. Dr. Feldman left the room.
- E. SANFORD FELDMAN (108-00) was visited 9/30/04. He has revised his protocol to include an explanation of *B. anthracis*. Dr. Feldman has done the corrections requested and his protocol was approved unanimously. Following discussion of Dr. Feldman's Sterne Strain of *B. anthracis*, Dr. Leonard reported that he had received an inquiry about Dr. Scheld's possession of *B. anthracis*. The caller, who wished to remain anonymous, was concerned that Dr. Scheld may have acquired strains of *B. anthracis* in an unauthorized manner. In response, to the inquiry, Dr. Leonard asked Dr. Scheld via email if he was in possession of any strains of *B. anthracis*. Dr. Scheld replied that he did not have any strains or plasmids. He only has the lethal toxin. The committee is aware of his toxin possession. Dr. Scheld stated that he intended to acquire non-toxigenic strains in the future and would notify IBC at that time.
- F. JEFFREY WIMSATT has made corrections since last month. He has also explained what he needs. He does not have a current lab, but he needs to have approval so he can get approval from the ACUC in order to apply for an NSF grant. He asked if perhaps we could give him provisional approval. The committee felt that there was not enough reason to believe that the animal rooms in the new building,, MR6, will be adequate containment for the rabies-infected bats he wants to have there. The facility was designed for laboratory rodents and rabbits, but not wild caught flying mammals. Unless other adequate vivarium space is identified, the committee cannot provisionally approve him for work with animals for which there are no facilities nor any planned in the near future. Also it was not clear whether Dr. Wimsatt had any experience working with rabies virus in the laboratory or administering it to wild animals kept in captivity. The committee unanimously voted to disapprove this protocol.

3. Protocols with new lab visits or corrected visits:

- A. FELICIA GASKIN ((097-99) was last visited 4/2/04 however she had never completed her outstanding items. She has done so satisfactorily according to Jean Gratz who visited her last week. She was approved unanimously.
- B. KENNETH PFISTER (120-01) was visited 4/3/05. He was re-inspected last week and had corrected his open items. He was approved unanimously.
- C. MILAROS HUERTO is a new PI and was visited 4/5/05. She was re-inspected yesterday and everything was corrected. She was approved unanimously.
- D. MILTON BROWN is a new PI and was visited 4/11/04 and was in very good order. He was approved unanimously. Also, Dr. Mann suggested that we tell them about the free lab gowns at MERCY since it appears that the Chemistry Department is not currently funding lab coat laundering. Dr. Brown is currently providing funding.

3. Protocols with current lab visits:

- A. AMY BOUTON (074-99) was last visited 10/25/04. She was approved unanimously with this change.
- B. THOMAS BROWN (122-01) was last visited 12/19/03. He needs to identify his organism as Methicillin resistant and the question C is not N/A. It needs to be answered BSL2. Provisional approval is given pending receipt of these changes in the protocol.
- C. JEROME FERRANCE (185-04) was last visited 5/3/04. He was unanimously approved, but next year we need to ask him to update the formatting.
- D. GREGORY HELMS (051-98) was last visited 8/16/04 and he says there are no changes in his protocol. He also continues to have Dr. Hankins as personnel. He says that Dr. Hankins is still interested in the work and consults. He has an adjunct position with the University. In I, he needs to remove the reference to Universal Precautions and substitute it with the OEHS Blood borne Pathogens research training. Hospital orientation is not suitable. He needs to give us a list of his cells in the recombinant section. He was approved pending these changes.
- E. CHARLES FLICKINGER (038-98) was last visited 3/4/04. He needs to have the symbols changed throughout since HTML doesn't take Greek Symbols. Also, he needs to tell us the species of Burkholderia and Salmonella he has and how they are being used. He was approved pending these changes.
- F. DAVID JONES (149-03) was last visited 3/31/03. His protocol had been previously read and has been corrected. It was apparent that whoever wrote his protocol had not attended the Blood borne pathogen class since they state they use 100% bleach to clean up spills. They need to list the cell lines they use. The protocol was tabled until the changes are made and we find out about the classes.
- G. BENJAMIN GASTON (076-99) was last visited 1/20/03. His protocol had been previously read and has been corrected. His protocol is approved.

- H. GEORGE VERGHESE (166-03) was last visited 6/23/04. This is a new protocol that we got yesterday. He needs to list his cell lines prior to his protocol receiving approval.

4. Renewal protocols who need a lab visit:

- A. JAMES BENNETT (088-99) was last visited 8/23/99. Dr. Bennet needs much more detail in his protocol. He'll also need a lab visit.
- B. DANIEL ENGEL (102-00) was last visited 1/14/00 and has revised his protocol from that originally given to the committee. He needs several corrections including listing viral vectors at BSL2. He needs to include that adenovirus causes respiratory disease in humans. He'll need a lab visit.
- C. KLAUS LEY (042-97) was last visited 4/16/02. Dr. Ley needs to add information about his transgenic mice and he'll need a lab visit.
- D. RONALD TAYLOR (049-98) needs a new lab visit because his renovations have been finished and he's moving to his permanent labs. He would like an expedited approval and expects to have his hoods inspected this week. There are not changes to his protocol except for the rooms. He needs to list his cell lines and schedule a visit.
- E. REID B. ADAMS (114-00) needed to give us a list of the vectors he's using and needed a lab visit. He said that he's no longer doing any vector work. The committee agreed to remove him from our database and if he wants to do work in the future, he can submit a protocol.
- F. SARA PARSONS (007-98) was last visited 11/7/02. Her protocol was received today. She needs to remove references to Sonia Pearson-White and do a lab visit.

5. New Protocols:

- A. JAY FOX has not revised his protocol as yet. This protocol was tabled until revised.
- B. NENA FOX has not revised her protocol since the committee last saw it. This protocol was tabled until revised.
- C. IGNACIO PROVENCIO has revised his protocol since the committee last saw it. He needs to delete a large portion of the protocol, which is excerpted from the BMBL. He need only reference the BMBL. He'll need a lab visit.
- D. NASSIMA TIOURIRINE would like to have expedited approval since they are doing clinical work and are starting as soon as they can get approval. They would like to have the lab visit any time this week on Wednesday, Thursday or Friday morning. Since no other group is overseeing the use of BSL2 materials at this lab, and since they have NIH funding, everyone believed that it's appropriate to have the IBC do this protocol. They need to revise question F so that its answer is only "yes".

6. New business.

- A. Dr. Leonard gave everyone a proposal for a policy on biotoxins that he'd like the Committee to consider adopting. It would include some tables he'd like to

have on the webpage showing the LD50. He will send around the proposal to everyone by email for comments.

- B. Dr. Leonard also floated the idea of having the meetings during the day. Maybe we could try this during the summer months. He said that everyone should just think about it.
- C. It was decided to decide about the next meeting by email.

Institutional Biosafety Committee  
Minutes  
May 23, 2005

Barbara Mann, acting Chair, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Peter Ernst, Sanford Feldman, Tom Leonard, Susan Kiley, and Marjorie Maxey.

I. Protocols with new lab visits:

- A. R. ARIEL GOMEZ (084-99) visited 4/28/05 by Kiley, Leonard and Gratz. He was approved by email vote. His approval was confirmed by another unanimous vote.
- B. RICHARD L. GUERRANT (009-96) visited 4/29/05 by Gratz. He was approved by email vote. His approval was confirmed by another unanimous vote.
- C. JAMES K. ROCHE (111-00) visited 4/29/05 by Gratz. He was approved by email vote. His approval was confirmed by another unanimous vote.
- D. RONALD TAYLOR (049-98) visited 4/49/05 by Gratz. He was approved by email vote. His approval was confirmed by another unanimous vote.
- E. KLAUS LEY (042-97) visited 5/5/05 by Hammarskjöld, Mann and Gratz. He needed his new lab manual completed, but it still did not have signatures when Jean Gratz checked it on Monday. She did not recommend him at this time and Gloria Bowers said that he's been very difficult about the changes he needs to make to his protocol. The committee had numerous changes that he needs to make in his protocol and he was tabled until his lab manual and his protocol were complete.
- F. GAIL WERTZ visited 5/5/05 by Hammarskjöld, Mann and Gratz. Her lab has not been moved as yet, but she needs approval before she can get her grants moved. She was given a preliminary approval by email. Everyone agreed that she has made excellent responses to our needs and she was approved unanimously. We can schedule a lab visit when she has arrived. Her new number is 214.05.
- G. MILTON BROWN (211-05) visited 5/17/05 by Mann and Gratz. His chemistry section has been approved and now his Experimental Therapeutics Core in Jordan Hall, which he shares right now with Mike Weber's lab, needs approval. His chemistry rooms are approved, but he has added rooms in Jordan Hall. He needs a lab manual for the Jordan Hall group. He needs to have everyone do the training. He has made changes to make it easier to read his different parts of the protocol without confusing the two sites. He has been very conscientious and he was approved pending the training being completed and his lab manual being completed.
- H. RONG LI (139-02) visited 5/17/05 by Mann and Gratz. He has revised his protocol. He needs to get a filter on his vacuum tube and finally to get signatures from anyone sharing the tissue culture room with him. He had some confusing things still on his protocol and he needs to have his protocol

corrected before we can approve it. He has completed all of his lab items and is in good shape there. He has said he would go to training also. He was tabled.

- I. SARAH PARSONS (007-96) visited 5/19/05 by Kiley and Gratz. Lab visit was in good order. Jean Gratz is going to try to get them to use CMCs rather than the waste boxes, but otherwise they were good. They did not have any open items other than the garbage which they will follow-up with Jean Gratz. They were approved unanimously.
- J. BRENT FRENCH (73-98) visited 5/19/05 by Kiley and Gratz. He has some signatures to get for his manual and Jean Gratz was going to check on him Monday. He had everything in order in his lab when Jean Gratz returned. He still needs his training and has said that he will be doing it. He was approved unanimously.

2. Protocols, which have current lab visits:

- A. BARRY GUMBINER (182-04) was last visited 4/27/04. He has no changes. His protocol was in order and he was approved unanimously.
- B. JO HENDLEY (033-96) was last visited 11/10/03. He has added some microorganisms but they are only for controls for the tests that he runs from the samples from patients. He needs to explain in his protocol what he is using the bacteria that appear in his protocol. There was a question as to how he is getting rid of urine, but Tom Leonard said that it's fine as written. He was tabled until he resolves the bacteria.
- C. JOANNE LANNIGAN (159-03) was last visited 7/7/04. She has no changes. She runs a core facility and there were no problems with her protocol. She was approved unanimously.
- D. PETER LOBO (023-97) was last visited 5/5/04. He has no changes. It is confusing that he is showing HIV as a BSL3 and then he talks about using it under BSL2 conditions in his lab and BSL3 conditions in the Thaler lab. Since he is under Rekosh and Hammar skjöld's lab manual when operating in the Thaler Lab, he needs to explain his BSL2 work that occurs in his BSL2 lab and then talk about moving material to the Thaler lab and just explain what work is done there. The bulk of his protocol should be about his lab in the Multistory. He's been tabled until he makes those changes.
- E. JAMES MANDELL (175-04) was last visited 3/23/04. He changed his protocol to conform to his previous protocol by adding cell lines which are frozen right now, but which he plans to work with in the next year. Dr. Leonard did not believe that he had been to training and wanted to check on him. He needs to describe his cell lines. He's tabled until those items are done.
- F. DAVID MULLINS (202-04) was last visited 10/27/04. He has changed his protocol so it does NOT read Variola. There are errors still in his protocol about poxes. He should only be describing vaccinia and not making reference to other poxes. Also he has stray sentence particles that he needs to delete. He's tabled until he changes his protocol.
- G. M. SMITH (179-04) was last visited 12/17/03. He doesn't have any changes. He looks to be in fine shape. He was approved unanimously.

- H. WEI YUE (194-04) was last visited 6/18/04. He doesn't have any changes. He needed no changes and was approved unanimously.
- I. JOHN LAWRENCE was last visited 1/6/05. He's made some requested changes to his protocol. He has completed everything and was approved unanimously.
- J. MICHAEL WEBER (022-96) was last visited 6//17/03. He changed his protocol. He has other changes to make. It is just too confusing in how he has written his protocol. He needs to organize it and then resubmit. His protocol was tabled.

3. New protocols and Renewals that need new lab visits:

- A. CAMERON BASS (144-02) last visited 10/15/02. He needs a new lab visit.
- B. CLAIRE CRONMILLER is not doing any current work, but is storing *Staphylococcus aureus* in a locked freezer. New protocol. She was approved unanimously since she is only storing material now. Dr. Leonard had seen the freezer.
- C. VICTOR ENGELHARD (016-00) last visited 11/25/02. He's made changes to his protocol but he hasn't done a risk assessment. His protocol was lacking in some information and needs to be improved. He needs a lab visit.
- D. PETER ERNST (124-01) last visited 9/14/01. He's added to his protocol. He needs to do a lab visit.
- E. ADAM GOLDFARB (104-00) last visited 3/20/02. He needs to do a lab visit.
- F. FREDERICK HAYDEN (053-98) last visited 9/27/01. He also needs to tell us who will be responsible for his lab when he is on sabbatical.
- G. PETER HEYMAN (128-01) last visited 9/10/01. He needs to explain if he does culturing in his lab. We can't tell from his protocol. He also needs to do a lab visit.
- H. KEVIN HOGAN (137-02) last visited 4/2/02. He needs to do a lab visit.
- I. ADAM KATZ (140-02) last visited 9/4/02. He needs to supply much more information. He also needs to explain how he gives cells to people. He needs a lab visit.
- J. SUSAN KIRK new protocol. She needs to do a lab visit.
- K. TIMOTHY PRUETT (037-00) last visited 11/20/02. He needs to do a lab visit.
- L. THOMAS A.E. PLATTS-MILLS (134-02) last visited 3/14/02. I emailed him that he needs to put his protocol online. He gave us a paper copy. I haven't heard from him yet about the new protocol. He's on leave and we may want to have Dr. Woodfolk from his lab look at this. He will need a lab visit.
- K. JEFFREY HOLT (142-02) was last visited 9/18/02. He has no changes. He needs a lab visit.

4. Other business:

- A. We have completed 30% of the protocols.
- B. Dr. Leonard wanted to speak with everyone about the ACUC and whether we want more information from PIs about what they do with animals. Currently the IBC is not assessing how the biological material is used in the animals or

determining if the application is acceptable. Dr. Feldman said that when he first came to this University he asked the IBC to determine a containment level for the biological material that was being used in animals. At the time the ACUC was trying to determine this, Dr. Leonard said that currently there is a problem with Dr. Roche who is using ricin under Dr. Obrig. He wants to aerosolize it in order to give it to mice. Dr. Leonard is concerned that this might mean that the ricin containment might be increased from BSL2. Right now he's afraid that the ACUC may think that the ricin can be used in any way that the PI desires despite the protocol not describing any aerosolization. Dr. Leonard feels that we may approve a specific material but not its use in animals. Dr. Ernst felt that most of what is done is not a problem. Someone also commented that there are 3 people on both committees and that it's unlikely that something would be approved without someone knowledgeable knowing about it. Dr. Feldman said that there is also a potential problem in getting vaccinations for animal workers and also know who needs such vaccinations since more and more people come from overseas and their vaccination history is somewhat confused. Dr. Leonard asked everyone to think about adding something about the animal work to be done. Also, Vaughn Kowahl will be at our next meeting to discuss changes we may want in our online system.

B. A new meeting day will be selected by email.



Institutional Biosafety Committee  
Minutes  
June 13, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Tom Leonard, Susan Kiley, Barbara Mann, and Marjorie Maxey. Vaughn Kowahl attended the early part of the meeting.

Due to the comments by Dr. Engelhard, it was agreed that we'd have a comment box added to the registration so that we can be aware of how people find the registration. We asked that each section be able to be approved separately so that someone can be approved one item, but not another. We discussed the possibility of seeing the current proposal and the approved proposal side-by-side so that everyone can see any changes. Also, it was suggested that perhaps the changes could be done in another color such as red so everyone knows it. Suggested that different changes would have different values, i.e. changes in personnel are less of a problem than changes in materials. We asked to add the Lab phone number and the messenger mail address. Under toxins we need to make a comment to define what we're concerned about for the LD50.

We discussed separating viruses, but never agreed how to do it. We do need to have specific viruses rather than families.

We did agree to define recombinant DNA so that people have a better idea of what information we want or provide a link to the guidelines so that everyone understands it. Suggested a note at the beginning of the document saying that we need enough information to understand what they are doing. Ask for a description of the vector system. Perhaps we should rephrase some of the questions that we ask. We need to ask for specific viral vectors and what percentage of the virus they are using. Also, we need to ask if it is replication competent.

We need to have plain language requesting information about transgenic mice. Right now PIs feel that the mouse core should get the approval. However since the PIs are using the transgenic mice we may need to ask for a list of the vectors in each mouse.

Dr. Hammarskjöld felt strongly that HIV could only be under BSL3 and not BSL2 since she did not feel that it is commonly used in regular BSL2 labs nor should it be used in them. She asked that it be removed from the BSL2 list.

It seemed unwieldy to add all the possible vectors to the recombinant DNA portion. It appeared that we needed the PIs to list the ones they use.

We found out during a lab visit that there was no place for non-human primates to be listed. This is very important to add.

There was a discussion of how much animal information we needed to have.

The committee also asked if everyone on the committee could get into the database to read the protocols rather than have to email the webpage since the addresses sometimes get changed due to various mail programs.

Vaughn Kowahl wants to discuss the online format and any changes we want.

1. Protocols with no changes and a current lab visit.

A. VICTOR ENGELHARD (016-00) He has various issues with the new system that he has told various committee members. He went through the entire document. Since Dr. Engelhard's lab visit is not due until November 11, 2005, the committee agreed to approve his protocol until that date.

2. Protocols with new lab visits:

- A. IGNACIO PROVENCIO was visited by Gratz and Leonard on June 1. His biosafety cabinet needed certification and to find out how his lab coats need cleaning. He advised Tom Leonard that he was taking the lab coat problem up with his department and he called about his biosafety cabinet and will follow up on it. He was approved unanimously.
- B. GEORGE BLOOM was visited by Gratz and Leonard on June 1. He had several open but the main item was taking the OEHSBPC. Others were disposal of Pasteur pipettes, CMCs use, chairs, and lab coats. He took the OEHS Blood borne Pathogens training with other members of his lab. He was approved unanimously.
- C. KEVIN HOGAN was visited by Gratz and Leonard on June 9. He had two chairs that had fabric covering. He has covered them and is setting about purchasing two appropriate chairs. He was very cooperative and started work on fixing his problems immediately. He was approved unanimously.
- D. JAY BROWN was visited by Gratz and Leonard on June 9. His lab was in good shape. He and his lab need to do training. He was approved unanimously.
- E. NINA FOX was visited by Gratz and Leonard on June 9. She keeps cell lines and sells them. There were several items in her lab: She needs to change out a chair that has fabric covering; she needs to have an eyewash installed; she needs to use 10% bleach rather than 70%; she needs to replace her Bunsen burners with touch plate burners; she needs to set up a laundry contract for her lab coats; she needs to start disposing of her sharps containers in the CMC container and not emptying them and using them again and finally she needs to remove a coffeepot and coffee container that she says she does not use but keeps for sentimental reasons. She has many items open and the committee decided to table her protocol until some of her problems were corrected. She did offer to help us find people who may not have sought approval, but use her cell lines.

3. Protocols, which have current lab visits:

- A. BRIAN HELMKE (164-03) was last visited 10/18/03. Everyone in his lab has had training. He was unanimously approved.
- B. JOHN HUNT (171-04) was last visited 2/17/04. He needs to tell us what cell lines he uses and what he does with them. His lab has not attended training.
- C. SUSAN KILEY (193-04) was last visited 6/18/04. She was fine and had training. She was approved unanimously.
- D. JAMES MANDELL (175-04) was last visited 3/23/04. Everyone has had training. He was approved unanimously.

- E. CHRISTOPHER MOSKALUK (078-99) was last visited 3/21/03. What is he doing with VSG? Also he needs to tell us which system he's using, FIV or HIV. Before we approve we need more information and since he's now doing virus work and had been doing human tissue. The committee asked for a lab visit so that we can see what he's doing.
- F. JERRY NADLER (136-02) was last visited 8/10/04. He was approved unanimously.
- G. JOHN PARSONS (070-98) was last visited 4/03/03. He needs to do a narrative and tell us what vectors he's using. After he's done this he's approved unanimously.
- H. THERESA PIZARRO (163-03) was last visited 10/28/03. We need to check her personnel to see if they have had training. She was approved unanimously pending checking her lab has had training.
- I. STEVEN POWELL (040-98) was last visited 12/17/03. He needs to explain his what kind of lentivirus system he's using. Also he needs to tell us which human derived tissue he's using.
- J. DAVID SMALLEY (197-04) was last visited 8/23/04. We recommend that Karen Root do the training. He was approved unanimously.

4. New protocols and Renewals that need new lab visits:

- A. ERIC DOBRATZ is a new protocol. He needs a lab visit and a better description.
- B. ADAM KATZ (140-02) was last visited 9/4/02. Dr. Feldman and Kiley want to go to this lab visit.
- C. RICHARD KENT is a new protocol.
- D. GARY KUPFER (103-00) was last visited 8/24/01. He needs a better description. He is using retrovirus vectors and a pseudotype with VSV. He needs a lab visit.
- E. JOEL LINDEN (105-00) was last visited 4/22/02. He needs a lab visit.
- F. GARY OWENS (089-99) was last visited 4/1/02 He needs to tell us which genes he's inserting. He needs a lab visit.
- G. CHRISTOPHER REMBOLD (006-99) was last visited 4/11/01. He needs a lab visit.
- H. MARK STOLER (061-98) was last visited 5/19/98 He needs to tell us if anything he's doing uses more than 2/3 of the gene. He needs a lab visit.
- I. RONALD TURNER (129-01) was last visited 11/10/01. He needs a lab visit and training.
- J. JEREMY TUTTLE is a new protocol. He needs a lab visit and training.

5. Other business:

- A. J. OWENS HENDLEY (033-96) wants to do a hotel study. Tom Leonard asked if he could have time to review this.
- B. RICHARD D. PEARSON does not have an active laboratory, but has Leishmania isolates stored in the laboratory of Dr. RICHARD GUERRANT and Dr. Guerrant has added it to his protocol. The IBC agreed to this.

- C. KEVIN HAZEN (017-97) is adding a person; new cell lines; a room where cells are grown. He needs a new lab visit since he's got a new room. He'll need one anyway in November.
  - D. W. MICHAEL SCHELD (041-97) was last approved 12/9/04 and wants to add *Plasmodium yoelii* 17XL, which he calls a BSL1 agent. He's asking for approval. I could not find that this is considered anything else but BSL1. No approval necessary.
  - E. VICKY NORWOOD wants to be exempted from using children's urine in a study. We were not able to pass the exemption for urine by email. There was a discussion as to whether this should be exempt. Urine from healthy individuals is not harmful. Several people asked how you'd know. If there were be blood in the urine it would not be exempt. Tom said that he would write a policy where urine, tears, saliva, perspiration, vomit from healthy people are exempt from the IBC approval for the committee to review.
6. Select new meeting day. We will select the new meeting day by email.

Institutional Biosafety Committee  
Minutes  
July 13, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Tom Leonard, Susan Kiley, and Barbara Mann. It was noted that we did not have any community members attending and we agreed to be sure that Marjorie Maxey sees the minutes and has a chance to express any concerns. Also, Dr. Herzig has said that he may have to leave the committee due to time constraints. It is taking more time than he had thought it would. Dr. Hammarskjöld suggested that she knew someone who may want to be a new member. His name is John Coyle and he's a former Post Doc from her lab who works for PRA in Charlottesville. Gloria Bowers will get his CV and forward it to Dave Hudson.

1. Protocols with new lab visits:

- A. CAMERON BASS (144-02) was visited by Tom Leonard, Shannon Indoe, and Jean Gratz. Their lab was exemplary. This lab is part of the engineering group. They offer both Hepatitis A and Hepatitis B to their lab due to the possible fecal contamination. They were approved unanimously.
- B. ADAM KATZ (140-02) was visited by Sanford Feldman and Shannon Indoe on 6/24/05. He uses human blood, cell lines and unfixed organs and tissues. His lab was in good shape. He asked questions about a good disinfectant for the human fat. He needed his protocol approved right away and he was approved by email on June 25, 2005. Dr. Feldman explained that they do animal surgery in one of the rooms. He suggested that they use a respirator for the surgery. Dr. Katz agreed to be sure that he gives stem cells to people approved to have BSL2 and that they have approval to put them in animals if relevant. His approval was acknowledged.
- C. ERIC DOBRATZ (229-05) was visited by Tom Leonard and Shannon Indoe on 6/29/05. He uses human cartilage from ear and nose. His lab was in very good order. He was approved unanimously.
- D. JOANNA GOLDBERG (059-98) was visited by Tom Leonard, Shannon Indoe and Jean Gratz on 7/7/05. Her lab was in good order and she and her lab were due to go to training the next day. The committee asked that she put the species name on her microorganisms. She was approved unanimously.
- E. JEREMY TUTTLE (223-05) was visited by Tom Leonard, Shannon Indoe, and Jean Gratz on 7/7/05. He had several issues. He needs to get the correct manual in place. He needed a transport container, an eyewash and to remove all the food and drink from one of the rooms. He needs to describe his transport since he is getting surgical discards, they are transported and there is transport from room to room. Since he has to do the transport, he should also do spell check to all for easier reading. He has done all of the items except his lab manual. His protocol is approved conditional upon the changes to his protocol and lab manual.
- F. NINA FOX was visited by Tom Leonard, and Jean Gratz on 6/9/05. She had numerous issues that needed to be resolved such as using a touchplate rather

than a bunsen burner in her hoods, sharps containers, eyewash, etc. She has responded very well to resolving these things and has most of them done. Dr. Leonard felt that she should be approved at this time. Dr. Feldman asked if Dr. Leonard had been able to find out about who gets her cell lines and if she asks if they are permitted to use them. Dr. Leonard said that he spoke to her regarding only giving cell lines to those approved to use them and she has agreed to allow us to look at the list of people to whom she gives cell lines. The committee unanimously approved her protocol.

2. Protocols, which have current lab visits:

- A. LARRY BORISH (115-00) was last visited 04/01/04. Dr. Borish and his lab personnel have not done any training. They are tabled until they do the training.
- B. JOHN CHIRGWIN (190-04) was last visited 06/10/04. Everything in his protocol is in good order. The description was very good. He was approved unanimously.
- C. WAEL EL-RIFAI (155-03) was last visited 02/17/04. He needs to remove RNA and DNA from the description. Since this is a very little change, he was approved unanimously.
- D. SHU MAN FU (085-99) was last visited 1/29/03. He needs to write an overview of his work and he and his personnel need to do training.
- E. JO HENDLEY (033-96) was last visited 1/20/03. We also need to approve the hotel study that he wants to do. He was approved unanimously.
- F. ALAN HORWITZ (100-00) was last visited 9/4/03. He needs to have his staff trained, but he was approved unanimously.
- G. ROBERT KADNER (200-04) was last visited 9/13/04. He needs to do an overview of his work, but he was approved unanimously.
- H. ANDREI KHOKHLATCHEV (167-04) was last visited 1/30/04. His protocol was fine and he was approved unanimously.
- I. DAVID MULLINS (202-04) was last visited 10/27/04. Second time. Janine Oliver needs training and we should send him a copy of the proposed policy on vaccinia. Also, ask him to declare which strain he is using. He was approved unanimously pending these changes.
- J. CHRISTOPHER MOSKALUK (078-99) was last visited 3/21/03. Second time. He needed to add some cell lines. He was approved unanimously.
- K. LISA PALMER (107-00) was last visited 3/4/04. She has changed rooms and needs a new lab visit. Also, no one in her lab has taken training.
- L. MICHAEL SCHELD (041-97) was last visited 12/9/04. Dr. Scheld has added B. anthracis to his registration, which he's never had before. Gloria Bowers has contacted him and suggested that he remove it from his protocol until such time that he is approved to have it under the Select Agent rules. He replied briefly and can give us more details Monday that he has a nonencapsulated BSL2 strain that he believes has been previously approved.
- M. MARTIN SCHWARTZ (1150-03) was last visited 11/29/04.
- N. CORINNE SILVA (055-98) was last visited 3/22/04. She needs to change her protocol to reflect the use of a shield and not goggles when she opens a liquid

nitrogen tank. She also needs to have some of her personnel get training. After she has completed these items, the committee is granting unanimous approval.

- O. DAN THEODORESCU (086-99) was last visited 7/15/04. His protocol was very good and was approved unanimously.

3. New protocols and renewals, which need new lab visits:

- A. JAMES BENNETT (088-99) was last visited 8/23/99. He did a fantastic job on his description and seems to understand prions. Dr. Leonard would like to send him additional information from the BMBL. He needs a lab visit.
- B. JOHN CASTLE (143-02) was last visited 9/25/02. He needs to get NIH/OBA approval for use of cloning toxin molecules. Perhaps he should delete this section until such time as he gets approval and then he can add it back. He needs a lab visit.
- C. JEFF CRANDALL (300-05) is a new PI. He needs to fix the area where human tissue is repeated 6 times and give an overview of his work. Since we have recently visited the crash test building and everyone is working under the same lab manual, which is exemplary, Tom Leonard asked if we could approve him without a lab visit. After some discussion to be sure that there could be no problems, his protocol was approved without a lab visit.
- D. JAMES LARNER (242-05) is a new PI. He needs to explain what he's putting into the retrovirus vectors. He needs a more extensive narrative also. He needs a lab visit.
- E. MICHAEL LAWRENCE (241-05) is a new PI. His protocol needed some changes, but he and his lab have not attended training. It was suggested that he do the training and then the protocol. He needs a lab visit.
- F. REDDI PRABHAKARA (230-05) is a new PI. He has to remove adenovirus from his protocol unless he is using adenovirus vectors. There is no adenovirus in human cell line 293, it is transformed by adenovirus. He needs a lab visit.
- G. YUN SHIM (232-04) is a new PI. He needs to put an introduction to his work and do a lab visit.
- H. MARGARET SHUPNIK (060-98) was last visited 5/13/02. She and her staff need to do training and do a lab visit.

4. Other business:

- A. MARK STOLER (061-98) He no longer does any cell culture work, prep work, or storing. Everything has been give to the Cell Culture Core to store for him. All the material his currently has is formalin fixed. He does not have anything to show in a lab visit. He's asking to be removed from the list. The IBC agreed to remove him from our list.
- B. VICKY NORWOOD was never resolved last time. Are we approving her waiver to use urine with healthy children? At the previous meeting, Dr. Leonard suggested that we develop a policy for handling human materials not covered by the Bloodborne Pathogen Standard. Dr. Hammarskjöld and several other members have reservations about not controlling human derived materials that are exempt from the Bloodborne Pathogen Standard such as

tears, saliva, urine, etc. Many examples were given such as EBV excreted in saliva or CMV in urine and institutions that regulate human body fluids such as the University of Rochester. Dr. Leonard expressed concerns about mandating IBC registration and approval for these OSHA-exempt materials, which may be excessively burdensome to the research community. Since these questions won't be resolved at this meeting, the committee decided to decide on a case-by-case basis at this time. Right now Vicky Norwood is using healthy children in her research, but Dr. Kiley believed that if it progresses, she might be using diseased children. Also, It was suggested that Dr. Norwood lyse the cells before she leaves the clinic where she will be collecting the samples. Dr. Kiley suggested that she might not be able to do this. It depends upon how she is doing her ELISAs. Dr. Kiley will speak with Dr. Norwood and see how she wants to do this portion of the research and what her future plans are and report to the committee. If she can't lyse the cells before she brings them to her lab, she may have to submit an application depending upon what she's doing.

- C. Biosafety Training Status. Dr. Leonard reported that 3 programs are now in place. The OEHS Blood borne Pathogens and Biosafety Training is used as a first time orientation and Blood borne Pathogens training. There is now an online site for annual renewal of the Blood borne Pathogens Training. There is also the Shipping class and online renewal.
- D. Vaccinia policy. Everyone got a copy of the proposed Vaccinia policy created by Shannon Indoe. There were several suggestions. We need to add the Ankara strain which Dr. Hammar skjöld thought might be the more prevalent one used at UVA. Also, we need to remove Variola since no one should be using it. Also, it was confusing in the first figure, that the Biosafety level which refers to the strain looks like it refers to the parent virus strain. The last column should be moved to the middle. Dr. Leonard said that he didn't think we needed to have people go to both UVA WorkMed and student health, but everyone can go to UVA WorkMed as long as they can pay. He'll make changes and update the committee.
- E. The next meeting will be Tuesday, August 9 at 4:30 p.m.



Institutional Biosafety Committee  
Minutes  
August 9, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Tom Leonard, Barbara Mann, and Marjorie Maxey.

1. Protocols with new lab visits:

- A. PETER HEYMAN (127-01) was visited 7/14/05 by Leonard, Gratz and Indoe. He does not culture anything, but has it done in the Hayden lab when necessary. He had everything in good order. He needed eyewash and was provided with it. His protocol was approved unanimously.
- B. KAREN FAIRCHILD (235-05) was visited 7/14/05 by Kiley, Leonard, Gratz and Indoe. They have to move their eyewash so it is accessible. She works with siRNA. She was approved unanimously.
- C. JAY FOX (238-05) was visited by Kiley, Leonard, Gratz and Indoe on. He needs to get eyewash in place; and some signatures. He also needs to be sure that there is no coffee in this lab. Although he had eyewash delivered to him, he had not completed his signatures. Due to his reluctance, he was tabled until he's completed.
- D. JAMES BENNETT (088-99) was visited by Kiley, Leonard, Gratz and Indoe. He has both a Core facility for Neuroscience and his own lab. He needs to get the manual signed, the chairs need to be removed or covered and be sure everyone has signed the manual and that the Core facility is using the updated manual. They were given some signs to put into place also. He still has some follow up on his lab to correct. It was pointed out that his risk assessment needs to be more complete. He was tabled until he gets these items cleared up.
- E. JOHN LARNER (242-05) was visited by Leonard, Gratz and Indoe. He needs to get his manual completed, put a HEPA filter into the vacuum flask, get a hand sanitizer for his TC and he needs an eyewash. Also, he needs to be sure to explain what retrovirus he's using in his protocol and what he's putting into it and expressing as well as remove E. coli from his BSL2 since he's not using an exotic type. His protocol was approved conditional upon consultation with Dr. Hammarskjöld regarding risks associated with oncogenic potential of his vector system.
- F. PETER ERNST (124-01) was visited by Leonard, Gratz and Indoe on 7/27/05. He needed a HEPA filter on his vacuum flask, but otherwise was in good shape. He's done everything he needed and he was unanimously approved.
- G. SUSAN KIRK (244-05) was visited by Leonard, Gratz and Indoe on 7/27/05. She needed a HEPA filter on her vacuum flask line, her biosafety cabinet will soon expire and everyone needs to sign the Hepatitis B page. Her lab items have been corrected. It was suggested that we advise her to rewrite section A so that it is not so confusing as to imply that she is working with human tissue. However she is approved unanimously.

- H. FREDERICK HAYDEN (053-98) was visited by Kiley, Leonard, Gratz and Indoe on 8/08/05. His lab was exemplary. He was discarding his Pasteur pipettes in the wrong container (CMC), but they have now corrected this. He was approved unanimously. However it was noted that he said that there might be people in the University who possess or are working with H2N2 influenza virus, whom we may want to find.
- I. MILTON BROWN (211-05) was visited by Mann and Gratz on 5/17/05 and they had several items to clear up including: their lab manual completed; signs and stickers; inspection of the Biosafety cabinet and lab coats. Jean Gratz said that she visited them and they had everything in good shape. He was approved unanimously.

2. Protocols, which have current lab visits:

- A. EDWARD BOTCHWEY (178-04) was last visited 3/24/04. He was approved unanimously.
- B. THOMAS BROWN (122-01) was last visited 12/19/03. It was suggested that his risk assessment was not thorough. He should also cover the fact that immuno-suppressed individuals run exceptional problems. Dr. Feldman also asked if we could write a letter about people wearing scrubs into the animal facility and then back into the hospital without any change. It was decided that both Drs. Feldman and Hammar skjöld would write separate letters. Dr. Brown's protocol was tabled.
- C. SHU MAN FU (085-99) was last visited 1/29/03. He has written an overview of his work and half of his personnel have done training. He's had most of his people do the training and they are continuing and have assured us that everyone will do it. He was approved unanimously.
- D. MASUMA ETO (197-01) was last visited 8/10/04. He has many spelling problems and grammatical errors that make reading his protocol difficult. He needs an overview and the experimental goals.
- E. ISA HUSSAINI (186-04) was last visited 6/2/04. We looked at him earlier and requested that he give us an overview of his work. He has complied and we approved him by email 8/1/05. His approval was confirmed unanimously.
- F. SHYR-TE JU (191-04) was last visited 6/10/04. He has incorrectly added E. coli to the description. We should ask him to remove this before he resubmits next year. Otherwise he was approved unanimously.
- G. KEVIN LYNCH (075-99) was last visited 3/4/04. He was asked to do a brief description of his work. He was approved unanimously contingent upon that change.
- H. BARBARA MANN (002-96) was last visited 3/10/04. She is adding a few more human specimen types and storage of M. tuberculosis. While discussing these materials with Dr. Mann, it was apparent that they were due to work by Erick Houpt. Everyone agreed that Dr. Houpt should separate his work from Dr. Mann's BSL2 protocol and make his own BSL2 protocol. It was decided that Dr. Petri's work is so similar to Dr. Mann's at this time that they should not be changed. However, it was something that the committee asked to review at the next renewal.

I.

3. New protocols and renewals, which need new lab visits:

- A. ALLAN DOCTOR (228-05) is a new protocol. Gloria Bowers had written to him when we received his protocol asking for more information, but he hasn't given it to us yet. He needs to make these corrections as well as have a lab visit.
- B. CATHERINE HEDRICK (099-99) was last visited 05/15/02. Dr. Hedrick needs to write an overview of her work and get a lab visit.
- C. GORDON LAURIE (308-05) is a new protocol. He needs to remove the genomic DNA from the list of human materials. Also, how will the human cell lines be used? He needs to remove the detailed list of precautions and provide a summary.
- D. IAN MACARA (303-05) is a new protocol. His protocol was in good order. Drs. Hammarskjöld and Leonard said that they were both available to visit with him Wednesday afternoon.
- E. THOMAS PLATTS-MILLS (134-02) was last visited 3/14/02. Dr. Platts-Mills needs to give better answers for questions B, C, E, F, I and J. He also needs a lab visit.
- F. PRABHAKARA, REDDI (230-05) is a new protocol. He wants to work with human cell lines as well as monkey cell lines. He needs to do a new lab visit.
- G. PROVENCIO, IGANACIO does not appear to be approved online. Tom Leonard feels that he was approved in June and asked Gloria Bowers to check on it.

4. Other business:

- A. THOMAS STURGIL advised us of a needle stick in his lab. His post doc came to us about it and is going to get his lab in shape since he's in need of a re-visit and training. Tom Leonard will arrange for an investigation of the needelstick and provide a report at the next meeting.
- B. How are we going to handle PIs who share a protocol? Right now there are Mann and Petri; Stornetta and Guyenet; and there may be others. The committee decided to do this on a case-by-case basis.
- C. Discuss the regulation of non-BBP human materials (i.e. urine). The committee reviewed many other policies on the matter and both Drs. Hammarskjöld and Feldman felt very strongly that human urine should be handled as BSL2. Dr. Mann said that she had asked Dr. Eric Houpt whether urine and saliva should be BSL2 and he said that universal precautions should be sufficient. Dr. Leonard felt that investigators working exclusively with saliva, tears, or urine may be adequately protected by following Standard Precautions as defined by CDC, and that full IBC review and BSL2 containment may be excessively burdensome in some cases and that the risk may not justify BSL2 containment in all cases. He suggested an expedited approval option that the IBC Chair could determine. He was also concerned that there may be numerous protocols generated by this policy. It was finally decided that research involving urine, tears, saliva and other human excretions

must be registered with the IBC. The IBC would determine the need for approval and containment on a case-by-case basis.

- D. **Coordination with Human Investigation Committee.** Dr. Leonard said that he is now on the HIC and that he has been speaking to them about there being a question on each protocol so that they can catch people who need IBC approval for us and we might catch those who need to do a HIC protocol. The language still needs to be resolved. It was thought that the interface between the two databases must be human so that Gloria and the HIC will do it at this time since separate computer people keep the databases.
- E. **Vaccinia Policy Update.** Dr. Leonard stated that all suggested modifications had been incorporated into the document with the exception of the table illustrating examples of highly attenuated strains for which vaccination is not recommended. He presented two options for the committee to consider and it was decided to combine information from both options for use.
- F. **The next meeting will be decided by email, but it was suggested that the first Monday after Labor Day, September 12 at 4:30 p.m. would be it.**

Institutional Biosafety Committee  
Minutes  
September 12, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), John Coyle, Sanford Feldman, Susan Kiley, Tom Leonard, Barbara Mann, Marjorie Maxey and Vaughn Kowahl from OEHS to discuss the database system. Dr. Hammarskjöld introduced Dr. John Coyle who had once been a post doc in her laboratory and now works for PRA in the Northfork Research Park. He is our new community member.

1. Vaughn Kowahl gave us an update of the changes we had asked him to make from the summer. His memorandum is included at the end of the minutes. We went through Dr. Mann's protocol to see the various changes that he has been able to make such as the comments box at the end of the protocol, each section can now be approved separately, adding lab phone number and messenger mail address, definition of recombinant DNA, removing HIV from BSL2 list and only including it on the BSL3 list. Dr. Hammarskjöld commented that we'll need to set it up so that HIV vectors can be in the BSL2 list. Dr. Hammarskjöld said that she would work on a list of vectors for use at the end of the viruses. Lentivirus and retrovirus needs to be removed and replaced with specific species. Before this can happen, Gloria Bowers needs to contact the people who currently have these terms checked and have them add their species in other. Vaughn Kowahl will give her a list of the PIs to contact and we'll delete the lentivirus and retrovirus terms when the specifics are named. The language in some of the questions and comments has been clarified such as in "other"; it no longer states that the materials are unapproved. He's set it up so that everyone can get into the protocols to read. Also, the personnel section will show the PI and the committee who is current in training. He's also included a section about non-human primates. Dr. Feldman suggested that there be a space for the species rather than the part of the monkey (i.e. tissue, blood, cells, etc) since it makes a difference as to how infectious it can potentially be.

There was also a long discussion about the toxins. We need to give Vaughn Kowahl the language for how we want the toxins described. There have been suggestions that we only do LD50's but if someone doesn't know the LD50 of their toxin, how do we determine appropriate restrictions. The University of Florida has the best website on this subject and Dr. Hammarskjöld asked Tom Leonard to please look into this.

Finally in order to put in the system where we can see the changes that the PI has made since the last time, we need to have each of the previously approved protocols checked to be sure that the protocol that was approved and filed is still the same protocol in the system and that the PI has not changed it. Vaughn Kowahl has said that this cannot be scripted and that Gloria Bowers will need to do it individually for all of the approved protocols.

2. Protocols with new lab visits:

- A. IAN MACARA was visited 8/10/05 by Marie-Louise Hammarskjöld, Shannon Indoe and Jean Gratz. His lab was in good order and he has no outstanding items. Everyone was pleased with his visit and Dr. Hammarskjöld said that she found him very careful and good in his understanding of the material he's using. He is one of the PIs who will need to change lentivirus to HIV vector. He was approved unanimously.
- B. ADAM GOLDFARB (104-00) was visited 8/30/05 by Tom Leonard, Shannon Indoe, and Jean Gratz. Dr. Goldfarb needed training; to put a sign on his tissue culture room; to get eyewash installed; to make minor changes to the manual and to obtain a new transport container. His laboratory was in good shape and he made all the changes he needed. He needs to describe which lentivirus and which retrovirus under microorganisms. Also he needs to tell us which genes he's using. He was approved pending the document changes.
- C. GARY KUPFER (103-00) was visited 8/30/05 by Tom Leonard, Shannon Indoe and Jean Gratz. Dr. Kupfer had an emergency and couldn't be at the meeting. He has made changes to his protocol. He needs to resolve the matter of shipping since his lab personnel had differing views; everyone in his lab needs the OEHS Blood Pathogens class and Dr. Kupfer can renew online. The chairs in the tissue culture need to be non-porous; since there is no sink in the tissue culture room, a hand sanitizer needs to be installed; the infectious waste needs to be labeled; and there needs to be a filter on the vacuum flask in the biosafety cabinet. Dr. Hammarskjöld volunteered to do a new lab visit. He was tabled until his new lab visit.
- D. J. DAVID CASTLE (143-02) was visited on 8/30/05 by Tom Leonard, Shannon Indoe, and Jean Gratz. Dr. Castle's lab was generally in good shape. He and his personnel need to get training; they need sharps containers in the tissue culture room; biohazard labels on the storage units and 2 cloth-covered chairs need to be replaced or covered. No one has been advised if everything is done as yet. He was tabled.
- E. MARWIN AL-SHAWI (071-98) was visited 9/8/05 by Leonard, Gratz and Indoe. His lab was in mostly good order. He needs to get training, acquire disposable lab coats and plumbed eyewash. He has already gotten the lab coats. He was in very good shape. He still has to get training. He was approved pending his training.
- F. YUN SHIM (232-05) was visited 9/8/05 by Leonard, Gratz and Indoe. His lab was very good. He needs a transport container, his BSC certified and a hepa filter on his vacuum flask. He will contact us as soon as he gets the biosafety cabinet certified. He had an incorrect phone number for the inspectors. He was in very good shape and has contacted someone about his biosafety cabinet. He was approved unanimously.
- G. JAMES BENNETT (088-99) was visited by Kiley, Leonard, Gratz and Indoe. He has both a Core facility for Neuroscience and his own lab. He needs to get the manual signed, the chairs need to be removed or covered and be sure everyone has signed the manual and that the Core facility is using the updated manual. They were given some signs to put into place also. They have everything corrected according to Jean 9/1/05. He was approved unanimously.

- H. JEREMY TUTTLE (223-05) was visited by Leonard, Gratz and Indoe. He needed to include cell transportation on his protocol and he had a manual, transport container, eyewash and food and drink issues to resolve in his lab, which was resolved per Jean Gratz. He has completed all of the outstanding items in his lab visit and his new protocol was just received. He was given conditional approval pending his changing his protocol about Onyango and either deletion of their mention or resolution of the training.

3. Protocols, which have current lab visits:

- A. THOMAS E. BROWN (122-01) was last visited 12/19/03. He needed to write a better risk assessment from the 8/9/05 meeting. He should still make some changes to his risk assessment. He was unanimously approved.
- B. ANINDYA DUTTA (206-04) was last visited 11/30/04. His protocol looked fine. He was unanimously approved.
- C. MASUMA ETO (197-01) was last visited 8/10/04. He has revised his protocol to correct grammatical errors that make reading his protocol difficult. He added an overview. He was unanimously approved.
- D. JOHN HUNT (171-04) was last visited 12/17/04. He needs to clarify his protocol. Everyone thought that he works with rhinoviruses. He was tabled until he tells us more.
- E. JAMES LANDERS (126-01) was last visited 5/3/04. He has advised me that only his personnel have changed. Dr. Feldman told the committee that Dr. Landers is also using *Campylobacter jejuni* and the Sterne strain of *Bacillus anthracis*. He was conditionally approved pending these changes.
- F. DEBORAH LANNIGAN (1159-03) was last visited 7/7/03. Her protocol was approved last spring and has no changes since. She was approved unanimously.
- G. KEVIN LEE (174-04) was last visited 3/22/04. He was approved unanimously.
- H. JIN ZHONG LI (198-04) was last visited 9/1/04. Dr. Li needs to give a better description and in particular #L in the recombinant section needs a better description of his work. He was tabled.
- I. ULRIKE LORENZ (092-99) was last visited 1/21/04. She was unanimously approved.
- J. RAGHU MIRMIRA (131-02) was last visited 7/16/04. He needs an introduction describing his work. He was tabled.
- K. BARBARA MANN (002-96) was last visited 3/14/04. She has removed Dr. Houpt and his work from her protocol. Since it appeared that an incorrect copy of the protocol was attached, it was decided that this protocol would be approved by email.
- L. TOM G. OBRIG (079-99) was last visited 1/29/03. We have manufacturers' description of the apparatus for anyone who wants to read it. The rooms have not been finalized since they are still negotiating with other investigators who use toxins in the vivarium. Dr. Leonard's question about the disinfectant and the concentration, dose and frequency has been added to the protocol. Dr. Leonard spoke to a gentleman from USAMRIID who said that they do similar

experiments only in a BSL3, class III biosafety cabinet and that he would not recommend using a lesser cabinet. The machine for the mice can leak according to the people who spoke with Dr. Leonard. Also, the USAMRIID gentleman offered to do the aerosol exposure part of the experiment for Dr. Obrig. Dr. Leonard spoke to Dr. Obrig who decided not to proceed with this work until he can get a class III biosafety cabinet. Dr. Obrig is asking for one in his next grant. Dr. Obrig is only using 75 mg of ricin and he'd need to use 100 mg to be considered a select agent. This protocol was tabled.

- M. STEVEN POWELL (040-98) was last visited 12/17/03. Dr. Powell mentions using human tissues and cell lines in his narrative, but does not declare their use. He needs to update his protocol. He was tabled until he gets his protocol updated.
- N. GEORGE RODEHEAVER (020-98) was last visited 3/14/05. He is adding stem cells from Dr. Katz's lab to his protocol. They are getting the appropriate training. He was conditionally approved pending training and changing language referring to stem cells. They are not cell lines, but primary human tissue isolates.
- O. KODI RAVICHANDRAN (069-98) was last visited 7/15/04. Dr. Ravichandran had overlooked his expired IBC and had renewed it just as we became aware of a problem regarding disposal of his sharps; a notice was sent to everyone. He also needs to rewrite his protocol with a description of his work and better answers to the questions.
- P. CRAIG SLINGLUFF (127-00) was last visited 4/23/04. He advised Gloria Bowers that only his personnel have changed. He has vaccinia listed in the protocol, but does not indicate a source or the strain of vaccinia. He was conditionally approved pending additional information and removing his 3<sup>rd</sup> person references to himself. We need to tell him to review the University vaccinia policy.
- Q. THOMAS STURGIL (004-96) was last visited 11/15/04 and has open items including lab coats, touch plate, vaccinia stored in a locked place; and Hepatitis B and Vaccinia page in their manual. They have just put their registration online and are in the process of completing the outstanding items. Some of the lab has gone to training.

4. New protocols and renewals, which need new lab visits:

- A. ALLAN DOCTOR (228-05) needed to include more information in his protocol. We are currently trying to schedule a lab visit with him and Jean Gratz is working with him to prepare for a lab visit. He had some minor changes about the transport. He needs a lab visit.
- B. ERICK HOUP (327-05) has a new protocol. He used to be on Barbara Mann's protocol. He needs a lab visit.
- C. AMIR JAZAERI (323-05) has a new protocol. He is taking over the lab and work of Laurel Rice was just registered as working with BSL0. We need to schedule his lab visit also. He added new information last week. He needs to make his answers clearer, and replace lentivirus with the type of lentivirus he's using. He needs a lab visit.



- D. EDWARD PEREZ-REYES (319-05) has a new protocol. He needs to have a clearer discussion of his protocol. He's also incorrectly stated that his vectors "can't infect living cells" when he means that it can't replicate. He also needs a lab visit.
- E. MARGARET SHUPNIK (060-98) was last visited 5/13/02. She's having difficulty getting the lab manual to download, but Vaughn is looking into it. She's getting ready for her lab visit.
- F. JULIE TURNER (237-05) was visited for Med Micro in 11/02. She has added her own research to the Med Micro protocol she had shared with Amy Bouton. She needs a lab visit.

#### 5. Other

- A. Discuss the meaning of the new OEHS signs on the doors. The signs that show BSL2 for both work and when there is only storage. It may lessen the value of a BSL2 sign since the same symbol is used for both research and only storage. Tom Leonard said that he had told the committee about the signs last year. But many of the committee members said that the signs are confusing. Some members said that they have found people who feel they don't need to have any other signs. Dr. Leonard said that he had not heard that there were any problems with them. OEHS has spent a lot of time developing them. The signs are necessary for emergency people who may need to know what they could find potentially behind a door.
- B. Change in Dr. Kadner's IBC protocol since Dr. Nakamoto has taken over his grant for the next year. Everyone agreed that Dr. Nakamoto should have the protocol in his name while he is responsible for the lab.
- C. New meeting date. We will decide the date for the next IBC meeting by email. The next meeting will be Monday, October 10 at 5:00 p.m.

Institutional Biosafety Committee  
AGENDA  
October 10, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), John Coyle, Susan Kiley, Tom Leonard, and Barbara Mann,

1. Protocols with new lab visits:

- A. RONALD TURNER (129-01) was visited 9/16/05 by Kiley, Leonard, Gratz, and Indoe. He needed to get training, but his lab has training. Everything was very nice. In a shared storage room, his lab believed that Dr. Hendley's lab had a food refrigerator and coffee in a place used to store BSL2. The committee wants Gloria Bowers to advise both Drs. Hendley and Turner to remove all of the foodstuffs. We requested that he get a touch plate, and he has emailed that he is doing this. He should have more of an explanation in his registration document of his non-rhinovirus materials and their use. He was given conditional approval.
- B. JULIE TURNER (237-05) was visited 9/16/05 by Leonard, Gratz, Indoe. She had the wrong version of the lab manual and needs to do it. Also, she's doing work with BCG in Tom O'Brig's lab under his protocol, but Dr. Leonard has asked that she include it in her protocol. She added that and her work in Dr. Hazen's lab, which hasn't begun yet. Finally, there was some discussion about the HEPA filter on the vacuum line in her BSC, but that was just a misunderstanding and there are hepa filters inside the canisters. The committee unanimously approved her BSL2 work conditional upon her completion of her lab manual. She needs to delete her BSL3 work until such time as she can pursue it so that we can indicate her BSL2 approval.
- C. GARY KUPFER (103-00) was visited 8/30/05 by Tom Leonard, Shannon Indoe and Jean Gratz. Dr. Kupfer had an emergency and couldn't be at the meeting. He was again visited 9/23/05 by Hammarskjöld, Gratz and Indoe. He needed to add the pMMM (Maloney virus) to the BSL2 microorganisms and give us a list of the genes he's expressing and the cell lines he's using. He also needed to make any changes to the lab manual to conform to the registration document changes. He needs to restrict access to the tissue culture portion of his lab. It's most easily done by closing the door when they're working there. He is in the process of getting his training completed. He only has one person left to have training. He was approved unanimously.
- D. VICTOR ENGELHARD (016-00) was visited by Hammarskjöld, Gratz, and Indoe. His tech was getting her shipping renewed and they were set to do their vaccinia counseling in mid-October for someone in their group who wants vaccination. Other than these on-going things, they did not have any problems. There was a discussion of the vaccinia rules and it was felt that the work med who counsels people about the vaccinations should make sure that employers (PIs) understand that they can give the work with more exposure to people who have been vaccinated and allow those who don't want to be

vaccinated to do the work where there is less exposure. He was approved unanimously.

- E. THOMAS PLATTS-MILLS (134-02) was visited 9/27/05 by Kiley, Gratz and Indoe. Dr. Platts-Mills was very late and Dr. Kiley met with him after everyone else had left. They were in good shape. They needed to change out some chairs or cover them with plastic by their BSC and they needed to put a HEPA filter in their vacuum flask. Otherwise they were in good shape. He was conditionally approved pending the HEPA filters being installed and the chairs being corrected.
- F. ERICK HOUPPT (327-05) was visited 10/4/05 by Leonard and Gratz. Most of their training has been done. They had some chairs to replace and new chairs have been ordered and are due in 4-6 weeks. They had HEPA filters installed in their vacuum line. He was approved pending checking on his chairs and hepa filter.
- G. EDWARD PEREZ-REYES (319-05) was visited 10/4/05 by Leonard and Gratz. His lab was in good shape. They are in the process of getting everyone trained. After re-writing his registration, he now mentioned that he only uses 4.6 KB of the HIV which totals at 9.8 KB and he may be exempt. He needs to be advised that integration is a problem. Also he needs to fill in the recombinant DNA section. He was approved with these changes.
- H. PRABHAKARA REDDI (230-05) was visited 10/5/05 by Leonard, Gratz and Indoe. He was in very good shape. He had already ordered his eyewash. His lab was in very good order. He was approved.
- I. AMIR JAZAERI (323-05) was visited 10/5/05 by Leonard, Gratz, and Indoe. He is taking over Dr. Rice's lab. He was in good shape with some problems. He and one of his personnel had done the renewal, but we have not record of their taking the actual training class. He said he was going to remove the adenovirus and lentivirus from the registration until such time as they actually do the work. Mary Dalton believed that the Human papilloma virus, which may be in the tissue, they work with, needs 50% alcohol rather than 5-10%. They may need to get a different box for their ethidium bromide. Dr. Jazaeri needs to either write that he's using HIV vectors, or he needs to make the above changes. Right now we can't continue until he does it. The committee approved the protocol with the adenovirus and lentivirus, but without the E. coli.
- J. JOEL LINDEN (105-00) was visited by Gratz and Indoe. Dr. Kiley was to have visited, but there was confusion about the time. There are changes that Dr. Linden needs to make to his protocol such as adding room numbers, human cell lines and human tissue, a description of his work, a better description of the risk assessment and also questions C, D and E. He hasn't been able to do these changes yet. However, for his lab visit, he didn't do the new lab manual. He also needs to have Environmental Services install a hand sanitizer for his Tissue Culture since it doesn't have a sink. They are in the process of getting training. Since Dr. Linden has several outstanding items, we've tabled his protocol.

- K. ALLAN DOCTOR (228-05) was visited by Kiley, Gratz and Indoe. He was in good shape. He needs to get a better transport container and emailed me that they had ordered one. Most of their training is completed. His protocol was approved unanimously.

3. Protocols, which have current lab visits:

- A. JOHN CHIRGWIN (190-04) was last visited 6/3/04. He was approved unanimously.
- B. ROBIN FELDER (039-97) was last visited 9/13/04. He needs to cut and paste the section from Invitrogen virapower to the end of the vectors and move them to the recombinant DNA section. He was approved with the changes.
- C. MARIE-LOUISE HAMMARSKJOLD (025-96) was last visited 9/8/03. She has no changes. We need to add EBV to her protocol. She was approved unanimously.
- D. ERIK HEWLETT (021-00) was last visited 9/3/03. He made changes to his protocol. I marked them on the hard copy. He was approved.
- E. PETER LOBO (023-97) was last visited 05/05/04. He had changes to his protocol to make. He was approved unanimously.
- F. RAGHU MIRMIRA (131-02) was last visited 8/30/03. In his registration document, he needs to put the recombinant vectors into a recombinant DNA section. He was approved conditional upon this change. He was approved conditionally upon doing the recombinant portion of the registration document if it applies to his work. If it does not apply to his work, then he needs to explain why it doesn't.
- G. BARBARA MANN (002-96) was last visited 9/13/04. We need to approve her protocol without Dr. Houpt in it. Her protocol as approved unanimously.
- H. STEVEN POWELL (040-98) was last visited 12/17/03. He had changes to make to his protocol. The committee had a question as to the remark that the experiments had less than 2/3's of the viral genome. Dr. Hammarskjöld believed that it was more like 80% and asked that we get clarification. However since there was enough information and the recombinant DNA portion was completed, he was approved unanimously.
- I. KODI RAVICHANDRAN (069-98) was last visited 7/15/04. He had changes to make to his protocol. He was approved unanimously.
- J. DAVID REKOSH (026-96) was last visited 9/8/03. He doesn't have any changes to his protocol. He needs to have some corrections to his punctuation. His protocol was approved unanimously.
- K. DENNIS TEMPLETON (176-04) was last visited 3/23/04. He was approved unanimously, but the letter must include a reminder to read the Vaccinia Policy online.

4. New protocols and renewals, which need new lab visits:

- A. BRUCE GAYLIN he and Dr. Thorner below share space. He and Dr. Thorner are having a lab visit next week.
- B. MING LI (328/05) He needs to do a lab visit.

- C. ROBERT NAKAMOTO (064-98). He is taking over Dr. Kadner's protocol. He needs to have a lab visit.
- D. ROBERT SAWYER (029-96) was last visited 10/10/01. He needs to have a lab visit.
- E. JASON SHEEHAN (332-05). He needs to have a lab visit.
- F. DR. MICHAEL THORNER (056-98) He and Dr. Gaylin are having a lab visit next week.
- G. JUDITH WHITE (080-99) was last visited 11/20/02. She needs to have a lab visit.

5. Other business:

- A. During the protocol discussion, the committee spoke about the Vaccinia Policy and decided to email all of the vaccinia users of the change. Dr. Leonard will write an email directing PIs who list Vaccinia on their registrations. Dr. Hammarskjöld will look it over before it goes out. Barbara Mann suggested that Vaughn provide a link from the registration document to the Vaccinia Policy so that PIs can look at it when they're doing their registration.
- B. Discuss doing more renewal lab visits with Biosafety staff. We have a backlog of renewal lab visits of about 15. It has not been decreasing despite the increase in lab visits. Everyone agreed that Jean Gratz and Shannon Indoe are doing a very nice job. It was agreed that they can do the renewal lab visits which are routine. If someone is changing a material, or somehow significantly changing their registration or if the committee asks that special care be taken with the lab visit due to problems with the PI, then they won't be able to do it. In the future, the committee will say if renewal lab visits are routine or not.
- C. Jim Bolton from the Center for Applied Biomechanics has a question about adding space to their facility. They are experiencing a space crunch. They want to put locked chest freezers that contain biological specimens such as body parts into a sea container, which is similar to that which is used on trucks. It would be at the back of their current facility and would be locked and armed with their security system, which currently has locks and motion detectors inside. They have the impression that perhaps we may want them to keep everything within their current space. Everyone thought this would be fine. They should be sure to have it checked and added to their registration documents.
- D. Discuss SAMMIC Facility registration. There is a scanning position exposure group (CORE) who are working with PIs who sometimes have BSL2 animals and Tom Leonard is working with them so that they'll ask if they have IBC approval at appropriate times.
- E. Discuss "research portals". Ariel Gomez and Dave Hudson are interested in looking at a company who would combine all of the IRBs in one place for PIs to find and do more easily. It's designed to help PIs manage their compliance and hopefully help the various committees manage the PIs more easily. It would mean replacing Vaughn's software with a commercial product. The

company describes the product as seamless. Dr. Leonard attended a preliminary meeting about this and will keep us apprised of any developments.  
F. New meeting date.

Institutional Biosafety Committee  
MINUTES  
November 11, 2005

Marie-Louise Hammarskjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Susan Kiley, Tom Leonard, and Marjorie Maxey.

1. Protocols with new lab visits:

- A. MICHAEL O. THORNER (056-98) and BRUCE GAYLIN (056-98) were visited by Leonard, Gratz and Wilcox on 10/19/05. His lab was in good shape. He needs to be sure his Pasteur pipettes go into sharps containers. He needed a HEPA filter in his vacuum flask and get a better transport container. Dr. Leonard explained that Dr. Gaylin had a question about whether his cells should be killed in the biosafety cabinet or in the fume hood, which they were using. It was finally resolved that they were acting correctly. Both Drs. Thorner and Gaylin were approved unanimously.
- B. GARY OWENS (089-99) was visited by Gratz and Wilcox on 10/25/05. They need to be sure to have paper towels and soaps at the sinks. They are waiting for their dispensers. They need a better description of their work in their manual. They contacted us that everything is done. The committee all agreed that this protocol needs a better description of the recombinant DNA portion of their protocol. There looks to be errors in the dosages as well as not enough information. They could also use a description of the type of work they do in the beginning of the infectious portion. They were approved provisionally upon Dr. Hammarskjöld reading and approving their corrected description.
- C. THOMAS STURGILL (004-96) was visited by Leonard, Gratz and Wilcox on 11/03/05. Dr. Sturgill was very unhappy with the visit, but his Post Doc, Carol Chrestensen was very helpful and hopes to have Dr. Sturgill to class in December. He had to strike SF9 cells from his protocol and give more information in his submission. His manual was more complete in its description. Otherwise, the lab was in much better order than previous visits. It appeared that although he's using adenovirus and lentivirus, he's not describing any recombinant DNA. We need them to fill out that portion of the application.
- D. JASON SHEEHAN (332-05) was visited by Leonard, Gratz and Wilcox on 11/9/05. They need to get an eyewash and change out their cloth chairs for plastic chairs, which should be easily done. They were given conditional approval.
- E. ROBERT NAKAMOTO (064-98) was visited by Gratz and Wilcox on 11/9/05. Everything was in good order. Nothing was amiss. Everyone was pleased with Dr. Nakamoto and Igor Olekhovich. He was given unanimous approval.
- F. TIMOTHY PRUETT (037-00) was visited by Leonard on 11/11/05. Everything was in good shape. Everyone had done the training except Dr. Pruett. They needed to have a cloth chair removed and to stop recapping their

needles. He isn't growing up any virus, but only using isolates of Hepatitis B and C. Dr. Leonard felt that Jean Gratz and Shannon Wilcox should visit the lab again to be sure that nothing was forgotten or that he may need to have his shipping reviewed. He was approved conditional upon Jean and Shannon finding everything in order.

- G. MICHAEL LAWRENCE (241-05) was visited by Leonard, Gratz and Wilcox on 11/11/05. Everything was in good shape. His lab was stellar and he was unanimously approved.
- H. KLAUS LEY (042-97) was visited 5/6/05 by Hammar skjöld and Gratz. He had several items open among them the new manual wasn't completed and many people in his lab had not gone to training. He was tabled last May. Jean Gratz and Shannon Wilcox revisited him today and he had everything in order except his vacuum line needs a filter. Most everyone in his lab including the PI has done training. They had everything in order. They were approved unanimously.

Before we continued, Dr. Feldman left the room so we could discuss his protocol.

3. Protocols, which have current lab visits:

- A. SANFORD FELDMAN (108-00) was last visited 9/30/04. He's removing Burkholderia since he does not keep the kind that needs BSL2 containment. He's also making personnel changes and minor changes to language. He was unanimously approved and asked to come back into the room.
- B. RICHARD L. GUERRANT (009-96) was last visited 5/3/05. He's adding Clostridium difficile to his bacteria list. H was approved unanimously.
- C. ADRIAN GEAR (1151-03) was last visited 4/30/03. We tried to renew him by email, but many people were out of town. His work has not changed. He was approved unanimously.
- D. PAUL MATHERNE (083-99) was last visited 9/13/04. He doesn't have any changes. He was approved unanimously.
- E. AMY BOUTON (074-99) was last visited 10/25/04. She doesn't have any changes. She was the first person who was approved last spring. After a discussion, everyone agreed that she could delete the Ebola virus-like particles from the list of microorganisms since she describes them very well in the recombinant DNA section.

4. New protocols, changes in protocols and renewals, which need new lab visits:

- A. TOM OBRIG (079-99) has given us some additional letters indicating that he wants to do the aerosolized animals in the MR4 module and has a letter from Dr. Hewlett allowing him this space. He's also given us a letter indicating that Dr. Chad Roy of Ft. Detrick, an expert in Aerosolized ricin, will act as a collaborator for this work. After some discussion, the committee decided that the space (MR4 module) should be visited to see if it is sufficient for the proposed work. If Dr. Obrig wants a letter, the committee agrees to give a letter describing what needs to be done to use the ricin with the animals as an aerosol.



- B. COLEEN MCNAMARA (031-97) was last visited 4/23/02. Although she's due for a lab visit, her lab is only storing adenovirus and do not have any plans to use any BSL2 material this year. There were several questions about this protocol. Dr. Leonard has received questions about her work since she has had CMC problems and a fire in her biosafety cabinet. If she's not working with infectious material, she shouldn't have CMCs. Dr. Hammarskjöld asked if she still has cell lines. Everyone agreed to ask her to have a lab visit.
- C. XIAOWEI LU (329-05) is a new protocol. Dr. Lu needs a list of all of the insertions that he proposes. He will also need a new lab visit.

5. Other business:

- A. Discuss the registration of transgenic mice. Dr. Leonard had a handout from the NIH Guidelines about Transgenic Rodents. He said that he believes from reading this section that UVA needs to have a registration of all transgenic rodents irrespective of their susceptibility to infections. He'd like to set up the most effective mechanism to do this. Both OBA and ALACC can check into this when they visit. There are 3 sources at UVA right now, the Transgenic Core Facility and 2 investigators. Everyone agreed that any animal that is breedable should be registered. He and Dr. Feldman will do a short list of questions to send out to the committee. The questions will include what gene was added or knocked out, the promoter, or the target. It was hoped that this registration could be connected to the Transgenic Core Facility so that PIs could do this at the same time that they ordered the mice. As of now, the committee will grandfather in any transgenic mice that are already here. Dr. Feldman said that it might go more smoothly if Dr. Leonard spoke personally to each person who uses these mice and got some input. He said that it usually made compliance easier when the people who would be giving the information were approached more personally. Dr. Leonard hopes to have the questions for the next meeting.
- B. Look at the new Goldenrod and decide when to send the new notice for everyone to register with the IBC. Some of the grant administrators in each department are asking PIs to get their IBC approval before they do their grant submission. We need to advise Administrators that PIs don't need to do this. So far, we can give them letters that they are starting to apply. We haven't requested all of the PIs to register since 2003. We have only contacted BSL2 (total 178) and BSL3 (total 5) labs. We have not contacted the general database. It was suggested that we contact the Chairs of Departments to request that they have their faculty register and that they have all new faculty register. Everyone agreed that this was a good idea. Gloria Bowers would work with Vaughn Kowahl in getting a list of department heads. We'll need a letter for everyone.
- C. Dr. Hecht has not responded to many requests and may need an official letter. He is not on our database. We found that he is using human material when the Environmental Health people were doing the signs. It was agreed that Dr. Hammarskjöld should write a letter to the Chemistry Department Chair to request that he have Dr. Hecht comply with UVa/NIH requirements. Dr.

Leonard also suggested that we write up a procedure on how to handle these matters in the future. Dr. Hammarskjöld agreed, but wants to be sure that the committee retain its flexibility.

- D. Dr. Leonard asked Dr. Hammarskjöld if she had a chance to look at his Vaccinia Policy email and she apologized for not getting back to him and told him she'd do it shortly. Also, she'll get the vector list for Vaughn, but wanted to have a better idea of what Vaughn wants.
- E. Dr. Feldman said that he had heard from a contractor that they are being asked for quotes without the animal BSL3 and BSI3 labs included. Everyone agreed that it was a very shortsighted view of the future.
- F. New meeting date. No one had their schedules, but Monday, December 12 seemed to be fine with most people, but Gloria Bowers will inquire.

Institutional Biosafety Committee  
AGENDA  
December 12, 2005

Marie-Louise Hammar skjöld, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio), Sanford Feldman, Tom Leonard, Susan Kiley, Marjorie Maxey and John Coyle.

Dr. Leonard wanted to tell everyone about the CDC visit. There were 2 contractors that conducted the visit and it was in conjunction with UVA's select agent renewal.

Everything went well. They visited Kevin Hazen's proposed BSL3 although it is not currently used as BSL3 due to problems with the air handling. The CDC were very happy with the discussions with Kevin Hazen. They also spoke to Sanford Feldman and Barbara Mann. They looked at everyone's records (waste disposal, biosafety, training, etc.) Dr. Leonard will do a written report. It appears to that NIH will start visits shortly.

1. Protocols with new lab visits:

A. ROBERT G. SAWYER (029-96) was last visited 12/9/05 by Jean Gratz and Shannon Wilcox. He needs to have a plumbed eyewash. This has already been started with the Dr. Pruett with whom he shares the space. He needs to change out a chair in one of the biosafety cabinets. Everyone has done training except Traci Hedrick who will be doing it this week. He asked Jean Gratz if he should add enterococcus to his protocol. He is to get us the information of whether this material causes disease in healthy adults. Everyone thought that it would help him to research it since he will be using it. Also we should tell him to see Dr. Sifri since Dr. Sifri thought it should be used as BSL2. He was approved pending this research.

3. Protocols, which have current lab visits:

- A. DEAN KEDES (082-99) was last visited 1/21/04. He doesn't have any changes. He was approved, but we should ask if he still has human cell lines. He was approved with human cell lines.
- B. JERRY NADLER (136-02) was last visited 8/10/04. He is removing his lentivirus. He needs to list AAV. He was approved with AAV.
- C. LUKAS TAMM (177-04) was last visited 3/24/04. He doesn't have any changes. He was approved.
- D. TOM OBRIG (079-99) was last visited 7/4/04. He has deleted his description of the aerosolized work and added a description of what work he is now doing. He was approved.
- E. COSTI SIFRI (209-05) was last visited 1/20/05. He has added Francisella tularensis vaccine strain LVS to his protocol. He needs to add the description of his project with Francisellas. We should send some of the articles on it so he can see some of the problems associated with it. He was approved pending this addition.
- F. LARISA GUBAREVA (072-98) has no changes since her last approval. She was approved.

4. New protocols, changes in protocols and renewals, which need new lab visits:
  - A. MICHAEL SMITH (219-05) His protocol is new. He needs a lab visit.
  - B. SIDNEY HECHT (348-05) I have asked Dr. Hecht and his contact person, Zhijie Gao to give us more complete answers as well as an overview of his work. There was an article in the paper about his work with MRSA, but it's not listed. We should inquire about it. He does have a connection to an outside lab and this may be part of that work. He needs to have a lab visit.
5. Other business:
  - A. Update on transgenic mice. Since the transgenic mice must have an ACUC approval, we'll have something built into the animal protocol that can then cross over to the IBC protocol so that we will definitely pick up all the transgenic animals. We need to find a similar way to be sure we are picking up any transgenic plants.
  - B. Update on contacting Department Heads for IBC registration. It's unclear how we should contact the Department Heads to have them encourage their people to register with the IBC.
  - C. There was an announcement that there would not be any BSL3 or vivarium in MR6 due to expense. Everyone agreed that there would be difficulty in the future if there were no BSL3 space.
  - D. New meeting date will be done by email.

UVA (3PP)

Institutional Biosafety Committee  
Minutes  
January 24, 2006

Barbara Mann, Chairman, called the meeting to order. Members in attendance were Gloria Bowers (ex officio) John Coyle, Sanford Feldman, Susan Kiley, Tom Leonard, and Marjorie Maxey.

Dr. Mann introduced herself as the new Chair and acknowledged the former IBC Chair, Marie-Louise Hammarskjöld's contribution to the Institutional Biosafety Committee and the University during her years of service. She commended her in her uphill attempt to have the administration recognize the IBC and give it more support, including a new Biosafety Officer. She said that she was very appreciative of her work.

Protocols with new lab visits:

- A. LISA PALMER (107-00) was visited 12/16/05 by Shannon Wilcox and Jean Gratz. Dr. Palmer's lab was in good shape. She needs to change a chair to a cleanable chair. She had told Gloria Bowers that this was done. She was approved.
- B. JUDITH WHITE (080-99) was visited 12/21/05 by Shannon Wilcox and Jean Gratz. Dr. White's lab only needed an extra sign, which was sent to her. Tom Leonard said that both Shannon Wilcox and Jean Gratz were impressed with her and said that her lab wanted to do the right thing. She was approved.
- C. GARY OWENS (089-99) was visited 10/25/05. He needed to make changes to his protocol. There was insufficient information. Their protocol is better, but it still is not complete. Dr. Owen's Lab manager, Raines, is undergoing Chemotherapy so there has been a delay amending the protocol. They need to say what genes they are using and include much more detail as to what they are doing. Tom Leonard suggested that we approve them for 2 months so that his animal protocol can go ahead, and advise them they need to revise their protocol. Dr. Feldman suggested that Gloria Bowers call and speak to Brain Wamoff who does much of their recombinant work and tell him what is needed. He was approved for 2 months.
- D. JOEL LINDEN (105-00) was visited 10/6/05. He had outstanding items as well as the class to attend. He's completed the class and the items. He needs to clarify his Toxin Safety Plan, which they are sending to Jean Gratz. He was approved pending a positive resolution to the clarification on his Toxin Plan.

Renewals:

- A. KENNETH BRAYMAN (157-03) was last visited 6/6/03. His protocol was approved and he needs to get a lab visit before June 6, 2006.
- B. BRYCE PASCHAL (096-04) was last visited 8/17/04. His ACUC is being held up by our approval. He needs to add which genes he's inserting as well as explanation of what they do to his protocol. He was approved pending this change.

- C. MARTIN SCHWARTZ (1150-03) was last visited 11/24/04. He needed to have training and everyone on his personnel sheet have done training. He was approved.
- D. JOHN HAYES (203-04) was last visited 11/15/04. He was approved.
- E. KLAUS LEY (042-97) was last visited 5/6/05. During his lab visit there were several items that needed attention. Everything is now complete and his lab has received training. Considering the improvement to his lab and protocol, he was approved. However, Dr. Mann suggested that she, Vaughn Kowahl, the IBC Webmaster, Dr. Leonard, and Gloria Bowers meet and come up with suggestions for improving the protocol instructions so that the investigators will have a better idea of the specific type of information the committee needs to evaluate their protocol.
- F. PETER STUKENBERG (160-03) was last visited 8/26/03. He needs a lab visit. During his lab inspection we need to ask what risk the genes he is using pose to humans since he doesn't explain it. Dr. Kiley suggests that we may need a higher than normal containment since these genes may influence cell division. We need to ask for more information on what's being put into cells because of integration. This will be done in the lab visit.
- G. THOMAS BRACIALE (018-99) was last visited 2/7/05. We need to have them un-select pox since they are not using a strain that needs BSL2. Also, they should include the type of vaccinia that they are using. He was approved with these changes.
- H. SHAYN PEIRCE-COTTLER (201-04) was last visited 11/15/04. She needs to change her material to primary cells or tissue since from her description, she does not appear to be using cell lines. She's approved with this change.
- I. AMY TUCKER (118-01) was last visited 6/3/04. There were no changes to her protocol. She was approved.

#### New Business:

- A. Dr. Mann asked Dr. Leonard to begin with the Vaccinia Exposure incident. The exposure happened to a graduate student in Victor Engelhard's lab on January 4, 2006. The student had been vaccinated within the past 2 years and the vaccinations should be good for 10 years. The student is fine. Dr. Leonard said that when they investigated the issues related to this exposure, they found that even when people are vaccinated, they could still develop an ocular infection if exposed. It's recommended that this work be done in a biosafety cabinet when possible or use eye protection. In this case the student was wearing glasses, which may have prevented an ocular exposure. Dr. Feldman said that it isn't practical to do mouse tail injections in a biosafety cabinet. It is difficult to see what you are doing. Dr. Leonard said that we should probably include in the new Vaccinia policy a part about using eye protection. He's going to work up a paragraph about how to use eye protection with mouse and IV work. Also, he'll include where the medical follow up should occur, work

med or student health since the Student Health didn't seem to know what to do with the student.

- B. OBA incident report system. The OBA sent a reminder regarding incident reporting. Dr. Mann said she had discussed the Vaccinia incident with Dr. Leonard and both decided that this incident did not need to be reported. However in the future, if there were reportable incidents, she would like to submit to NIH a joint report from the Chair and the Biosafety Officer (Dr. Leonard). Since the Biosafety Officer does the investigation, she wants them to inform the IBC of any incidents and give the IBC the opportunity to comment and add any additional recommendations for the PI. Everyone agreed.
- C. Reorganization of the committee. Dr. Mann gave everyone a list of her objectives for the IBC. This includes having a monthly calendar on our website with deadlines for protocol and registration submission. We should have a cut off date for protocols of 1 week before the next meeting so that everyone would have time to review the protocols. She wants to increase the number of people on the committee to 8-10 people. She wants to request suggestions from the Chairs of the Departments. Some suggestions included someone from the Core Facilities, James Landers from Chemistry, Kevin Hazen, perhaps Jean Gratz in an ex officio position. Dr. Feldman volunteered to create a checklist for reviewers. We may want to offer pre-reviews for new PIs. The Biosafety Office would do the lab visits unless it's a new PI or the IBC wants to be included on a visit. Dr. Leonard would prefer annual visits. It's often a problem when a PI comes before the ACUC and they are also due to have their 3-year visit. A laboratory will be in good standing if they have a current lab inspection and their protocol has been approved. Dr. Mann would also like to have annual training for the committee through guest speakers and an orientation for new members. It was suggested that we get into the faculty handbook so that new PIs would find it easier to find us. Also, Dr. Feldman suggested that the VPR webpage should have a compliance page for compliance orientation for new PIs. Dr. Mann also hopes to complete a mission statement and a charge of responsibilities of IBC and BO as well as policies and instructions for the PI. Further, she asked that everyone think about having the meetings during the day.

The meeting ended with Dr. Mann asking everyone to review the IBC Charge that Gloria Bowers will email to them and to email her with any comments or changes. We'll also select the next meeting date by email.