The Scripps Research Institute

Carolyn Keierleber, Ph.D.
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April 4, 2006

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

Dear Edward Hammond:

Enclosed are copies of the Minutes from TSRI IBC Meetings since 1 May 2003. Personal information has been redacted.

Sincerely,

Carolyn Keierleber, PhD
Director EH&S

Enclosure

BIOSAFETY COMMITTEE
Meeting Minutes
July 9, 2003

Present:
Donald E. Mosier, Ph.D., M.D., Chair
J. Lindsay Whitton, M.D., Ph.D.
Eric Johnson, Ph.D.
Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.
Thomas Northrup, Ph.D., J.D
Richard Gulizia
Joyce Joseph
Alana Althage
Bruce Beutler, M.D.

Absent:
Ellen Trester
Dennis Burton, Ph.D.
Marta Perego, Ph.D.
Mark Yeager, M.D., Ph.D
Juan Carlos de la Torre, Ph.D.

I. OLD BUSINESS

A. The minutes of the May 15, 2003 meeting were unanimously approved after some changes.

B. In regards to the LCMV discussion from the last meeting, it was decided that each LCMV protocol be evaluated separately, dependent upon the strain being used. In the event of a project being designated at BSL-3, the Biosafety Office, in consultation with DAR, shall assign an animal facility that has HEPA-filtered exhaust.

II. NEW BUSINESS

A. Review of Recombinant DNA Registration Documents.

The recombinant DNA documents were approved unanimously.

B. Review of Microbiological Hazard Registration Documents.

1. #07-09-03M-02 Dr. [redacted]'s protocol

DAR is currently unable to provide animal housing appropriate for the segregation of the mice involved in Dr. [redacted]s Ectromelia project. Therefore, the project will take place in Dr. [redacted]'s tissue culture room. Mice will be kept in the BSC at all times. There is an SOP for the

animal portion of the project that will be distributed after the meeting.

A committee member questioned the method of biological waste disposal, specifically who will handle the waste. It was recommended that Dr. add a statement to MBH form, explaining this that will personally inactivate (autoclave) all waste. The committee voted to defer the protocol until all members had reviewed the SOP for animal procedures, and the above issue regarding sharps disposal has been addressed. The committee plans to vote by e-mail before Friday July 18, 2003.

2. #07-09-03M-03 Dr. protocol

Dr. project will take place in the BSL-3 Facility. A sub-committee of the IBC toured the facility and found it to be fully functional. An updated SOP for the project had been distributed to the committee prior to the meeting. The project, which will be of a relatively short duration, will consist of growing the virus, extracting RNA, and cloning, with only RNA fragments leaving biocontainment. Since the incubator in the facility is not a carbon dioxide incubator, the virus will be grown in Plexiglas boxes and gassed in the BSC. Dr. has chosen to use PAPRs for the project, although respirator use is not a requirement. It was mentioned that the MBH document should be updated to reflect the BSC information for the BSL-3 facility, as opposed to that of the facility. It was also suggested that the references to UV bulbs on the BSCs be omitted from the SOP, as UV light cannot provide decontamination within a reasonable time period.

3. #07-09-03M-05 Dr. protocol

The committee voted to defer final approval of the project until Dr. arrives at T.S.R.I., and a lab location is assigned. It was recommended that a new MBH form be submitted with the relevant lab information.

The Microbiological Hazard documents were approved unanimously with the exception of the two projects mentioned above.

C. Review of New Registration Documents.

The New Registration Documents were approved unanimously. The committee voted to include a narrative section on the new MBH registration form, which will describe how the agent is being used.

D. Salmonella Reclassification

Dr. [redacted] has submitted a request to reclassify attenuated strains of salmonella from ABSL-2 to ABSL-1. The probability of transmission of salmonella to other animals is low, but not non-existent. The Biosafety Officer spoke with a salmonella researcher from S.D.S.U. regarding this issue. The NIH Office of Biotechnology Activities told him that the local committee decides whether a reclassification is warranted dependent upon 1) whether it is a vaccine strain requiring amino acids for growth and therefore attenuated, and 2) whether data can be provided showing that no transmission between animals is taking place. The researcher's data, via a barrier study, showed that the salmonella he used was not air transmissible but was oral/fecal transmissible in mice. The committee voted to maintain the ABSL-2 classification. The IBC Chair will address a memo to Dr. [redacted] regarding the committee's decision, and this will also involve the IACUC.

E. Biosafety classification of CWD prions

Dr. [redacted] project is a novel experiment involving the use of deer and elk CWD prions. The committee had previously approved a protocol for the creation of transgenic mice expressing the deer PrP gene (the mouse PrP gene in knocked out). The injection of prion enriched CWD material into the mice has yet to be approved. The committee questioned whether the project should be classified as BSL-2, like the injection of mouse prions into normal mice, or as BSL-3, like the injection of human prions or BSE into mice. If the experiment works, the mice will shed infectious deer prions. It is unknown but unlikely that these prions would be transmissible to wild type mice. The risk to humans is also unknown (but unlikely). Autoclaving does not eliminate prion infectivity, but only lowers it. Incineration should follow autoclaving. The committee decided to classify the project at BSL-2, and request that Dr. [redacted] create a SOP addressing prion infectivity. Inactivation of the waste materials must follow the CDC guidelines, which specify autoclaving at 137 degrees Celsius for 4 ½ hours. Dr. [redacted] provisionally approved this project at ABSL-2 with the stipulation that an SOP

addressing prion handling and safety practices be adopted and submitted to the IBC for consideration. The project has not yet been sent to the IBC as a whole.

F. BSL-3 Containment Facility Reports

The Biosafety Office will provide a report to the IBC regarding the BSL-3 facilities, one facility per meeting. This month's report was on the [redacted] BSL-3 facility. [redacted] sent it out prior to this meeting. There were no questions or problems discussed.

The meeting was adjourned at 4:10 p.m. The next meeting is scheduled for Wednesday, September 10, 2003 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
May 15, 2003

Present:
Donald E. Mosier, Ph.D., M.D., Chair
J. Lindsay Whitton, M.D., Ph.D.
Mark Yeager, M.D., Ph.D.
Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.
Dennis Burton, Ph.D.
Joyce Joseph
Alana Althage
Marta Perego, Ph.D.
Juan Carlos de la Torre, Ph.D.

Absent:
Eric Johnson, Ph.D.
Thomas Northrup, Ph.D., J.D
Bruce Beutler, M.D.
Ellen Trester
Richard Gulizia

I. OLD BUSINESS

A. The minutes of the March 12, 2003 meeting were unanimously approved.

B. The IBC Chair asked if the [redacted] procedure manual had been completed. Dr. [redacted] will complete the manual. It was mentioned that several select agents have been removed from the CDC's list.

II. NEW BUSINESS

A. Review of Recombinant DNA Registration Documents.

The recombinant DNA documents were approved unanimously.

B. Review of Microbiological Hazard Registration Documents.

1. #05-14-03M-02 Dr. [redacted]'s and Dr. [redacted]s protocol

The project involves virus-like particle (VLP) immunization. An IBC member asked who would be performing the rabbit immunizations. The animal staff will perform them. It was suggested that Dr. [redacted] speak to Dr. [redacted] regarding the immunizations. In addition, serum storage will be required for all persons handling the VLPs before the start of the project. .

2. #05-14-03M-01 Dr. [redacted] is protocol

Dengue serology will be performed before start of the project. This was outlined in the provisional approval. Seropositive individuals may not work with the Dengue virus.

3. #05-14-03M-14 Dr. [redacted]'s protocol

This project is a slight modification of one already registered, and is also BSL-2. It involves genetically modified, replication-defective adenovirus. The Ad5 gene is replaced with a fiber protein gene, generating a construct with a different and unknown tropism. The IBC believed that the BSL-2 designation was rigorous enough, even with the tropism change, since the Ad5 vector is attenuated

The Microbiological Hazard documents were approved unanimously.

C. LCMV Biosafety Level Discussion

The NIH guidelines regarding LCMV place it in Risk Group 2 for Non-neurotropic strains and Risk Group 3 for neurotropic. One of the IBC members made the point that all LCMV replicate in the brain and are thus neurotropic.

It was stated that Clone 13 is a sub-clone of the Armstrong strain, and that the Armstrong strain is not considered to be particularly dangerous here in the United States. An IBC member felt that Coxsackie virus was just as hazardous to work with.

An IBC member mentioned that LCMV should be placed at BSL-3 if aerosols are generated. It was mentioned that tissue culture work involving modest amounts of LCMV would not be likely to create aerosols. There are more recorded incidents of accidental infection through self-inoculation than through aerosol transmission. Aerosol transmission is not considered to be a prevalent route of transmission among arenaviruses.

There have been no known accidents involving LCMV within animal quarters at TSRI. Animals generally express a prolonged high antibody titer, but immunocompetent mice are usually virus-free within ten days.

The committee decided that the biosafety level for LCMV protocols would be dependent upon the strain, animal use, and manipulations required and should be decided on a case-by-case basis. The IBC requires that the strain designation be listed on microbiological hazard registrations.

D. Mouse Virus Vectors at BSL-1/BSL-2 and ABSL-1/ABSL-2 Discussion

This discussion involved Dr. [redacted] work with a mouse stem cell retrovirus that was previously approved at ABSL-2. Dr. [redacted] wished to house the mice at ABSL-1. The IBC Chair asked Dr. [redacted] to apply at BSL-1/ABSL-1 so the whole committee could review the change in Biosafety Level. She applied with one change, the substitution of an ecotropic envelope for an amphotropic envelope, in the packaging cell line. The ensuing discussion revolved around the following, whether the agent could recombine with endogenous mouse retrovirus, and if so, would this recombination result in a unknown tropism.

An IBC member stated that any infectious agent should not be used in the regular animal rooms. It was decided that due to the perceived risk to breeding and immuno-compromised mice, the project should be maintained at ABSL-2. Dr. [redacted] has a similar project at ABSL-1. The Biosafety Officer will contact him regarding the project being changed to ABSL-2.

E. [redacted] Virus Discussion

Dr. [redacted] requested samples of the [redacted] virus from the CDC, and received them from Canada. They are being stored in a freezer in the BSL-3 facility until his project has IBC approval. He has submitted a BSL-3 application and an SOP, which were not received in time for review at this meeting. No animals are being used in this project. Dr. [redacted] has requested authorization to complete some preliminary work to obtain data for his grant application, which is due in two weeks. This has not been granted.

[redacted] is currently investigating maintenance upgrades for the [redacted] BSL-3 facility, which has not been used as BSL-3 facility in some time. Dr. [redacted] uses this facility for a BSL-2 with BSL-3 practices project involving lentiviruses and NHP work.

The [redacted] virus is aerosol transmitted and the BSL-3 facility to which it is assigned should be re-commissioned before the start

of the project. The ease of aerosol transmission seems dependent on the area where the isolates originated. The mortality rate is now at 17% and growing, being higher for those aged sixty and older.

The committee decided on several action items. 1.) Ensure a fully functional BSL-3 facility will be available for [redacted] work. 2.) Prepare a means of public communication regarding research here at TSRI, with the help of [redacted], [redacted]s. 3.) Create a sub-committee or have the entire IBC review the BSL-3 facility chosen in order to fully convince all members that the space is appropriate. The Biosafety Office will perform a review of all the facilities and report to the committee.

F. Bioterrorism Discussion

[redacted] will provide the committee with information he obtained at a conference regarding biosecurity measures. TSRI's CDC application for select agent use has been approved. The finalized security plan is due by June 12, and needs to be implemented by September 12. TSRI will meet the minimum security requirements necessary for compliance, as there are only a few labs using select agents. Issues regarding ID badge wearing, card key access, and lab personnel log-ins were discussed.

The meeting was adjourned at 3:45 p.m. The next meeting is scheduled for Wednesday, July 9, 2003 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
September 10, 2003

Present:

Donald E. Mosier, Ph.D., M.D., Chair
Dennis Burton, Ph.D.
Bruce Beutler, M.D.
Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.
Thomas Northrup, Ph.D., J.D
Richard Gulizia
Marta Perego, Ph.D
Alana Althage
Juan Carlos de la Torre, Ph.D.
Ellen Trester

Absent:

Joyce Joseph
Mark Yeager, M.D., Ph.D
Eric Johnson, Ph.D.
J. Lindsay Whitton, M.D., Ph.D

I. OLD BUSINESS

A. The minutes of the July 9, 2003 meeting were unanimously approved after some changes.

B. Dr. [redacted] MBH registration from the July meeting, which had been pending approval due to missing biosafety cabinet and facility information, was approved.

II. NEW BUSINESS

A. Review of Registration Documents.

1. #09-10-03-06 Dr. [redacted]s protocol

An IBC member questioned whether the project should require RDNA registration. The project involves the observation of gene expression, and does not require RDNA registration. The biosafety concern is in regards to a T cell line transfected with HTLV-1.

2. #09-10-03-12 Dr. [redacted] protocol

The use of R-DNA was also questioned in regards to this project. No R-DNA registration is required. The P.I. will be utilizing transgenic bacteria, which have already been registered, and other strains of bacteria that are not BSL-2. The project involves transforming the human pathogen, E. coli Strain ATCC 25922, into a murine pathogen.

3. #09-10-03-03 Dr. [redacted] protocol

   The committee decided to approve this project contingent upon the creation of a chemical hygiene plan, due to the toxin being used. The CHP will be distributed to the IBC members for approval. The CHP will cover PPE, hood use, and other agent-specific safety issues. It was mentioned that the MSDS for the toxin recommends the use of respiratory protection so respirators should be worn while working with the agent. This project is exempt from the select agent program due to the amount of the toxin being used. It was stated that only one more milligram of the toxin would be needed in order for enrollment with the program to be required. The committee recommended adding a section for the CHP to the toxin registration form.

4. #07-10-02M-07 (addendum) Dr. [redacted] protocol

   Dr. [redacted] protocol, which involved adding the use of mammalian cell lines to an existing Vaccinia registration, was given approval contingent upon the Biosafety Office obtaining more information about the MOSEC cells being used. The BSC40 cells being used are a derivative of human 293T cells.

The registration documents were approved unanimously with the exception of the two projects mentioned above.

B. Recommendations for New Registration Forms

The committee recommended that the Biosafety Office ensure that the project description section of the registration forms provides enough detail to determine what the project entails. It was also suggested that the decontamination section of the facility registration form have check boxes with the standard choices of 1% bleach, 10% bleach, NaOH, etc., instead of fill-in-the-blanks. The section should also provide a link to a web site with directions for bleach decontamination. Regarding cell line registration, the P.I. should be asked to provide additional information on cell lines that are not on the drop down list of the registration form. These "non-standard" cell lines can be added to the drop down list as they are registered. The Biosafety Office will contact Research Computing regarding the addition a link from the P.I. project folders on the new web

site to [redacted] email address so comments could be sent directly to her, and also regarding the merging of the various pdf files into one large pdf file, which would compromise an entire project registration. It was mentioned that all comments regarding the registration documents should be emailed to [redacted] by the Friday prior to the meeting.

The meeting was adjourned at 3:25 p.m. The next meeting is scheduled for Wednesday, November 12, 2003 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
November 12, 2003

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Richard Gulizia
Joyce Joseph	Marta Perego, Ph.D
Eric Johnson, Ph.D.	Alana Althage
Beth Ford, D.V.M.	Juan Carlos de la Torre, Ph.D.
Carolyn Keierleber, Ph.D.	Ellen Trester
Thomas Northrup, Ph.D., J.D	J. Lindsay Whitton, M.D., Ph.D

Absent:

Mark Yeager, M.D., Ph.D	Bruce Beutler, M.D.
Dennis Burton, Ph.D.	

I. OLD BUSINESS

A. The minutes of the September 10, 2003 meeting were unanimously approved after some changes.

B. The Biosafety Office will address an issue regarding a glitch in the Adobe program, which has been responsible for deleting the occupational medicine requirements from the Project Approval Form.

II. NEW BUSINESS

A. Review of Registration Documents.

1. #11-12-03-01 Dr. [redacted] s protocol

An IBC member questioned whether the project should require IRB approval. The project does not require IRB approval because it is an established cell line, although some cell lines do require IRB approval.

2. #11-12-03-07 Dr. [redacted] protocol

This project involves the use of West Nile Virus in mice, and the IACUC is currently awaiting IBC approval prior to reviewing it. The project description field of this application is missing, as it is an older format of the microbiological hazard registration form. The project

description can be found in the BSL-3 SOP manual, which is attached. This includes an animal/rodent control program that is targeted toward mosquitoes. The occupational medicine requirements are also listed in the SOP, and require all personnel with exposure to WNV to have a serum draw completed, including DAR staff. If the project is funded, it will not be until April, and the project will not commence until May.

The project will be performed within the MBB BSL-3 facility, where it will be monitored for compliance daily. An IBC member questioned whether this would be possible, due to the large backlog of projects waiting to use the MBB facility.

IBC approval of this project is contingent upon the new post doc in the _____ lab successfully completing BSL-3 training with _____ as well as receiving specific West Nile Virus training from someone within the _____ lab. A sub-committee of the IBC, consisting of Dr. _____ and Dr. _____ will ensure that this training is completed, and will report back to the IBC regarding this matter.

An IBC member recommended that the IBC find out who will be directly supervising work on the project, and who will be providing the West Nile Virus training to the new post doc. The IBC member also suggested that the IBC look into the exact background of the post doc, and have the lab include all of the conditions and changes discussed at the IBC meeting in writing.

3. #11-12-03-10 Dr. _____ protocol

A RDNA registration is already on file for this project. An IBC member asked how much of the toxin would be produced, and whether the toxin is on the select agent list. The LF/PA combination is not on the list. The LD50 was questioned, as were the disposal methods for the project. The committee decided to defer approval of the project until a toxin registration form was submitted, in order for their concerns to be addressed.

The registration documents were approved unanimously with the exception of the _____ application mentioned above.

B. CDC Inspection

Facilities with Select Agent registrations are subject to an inspection by the CDC. The CDC will be coming to inspect T.S.R.I. on December 4th and 5th. The Biosafety Office will be meeting with all of the P.I.s involved, will perform lab audits using biosecurity checklists, and will hold a practice session with each of the labs. The CDC officials will require a presentation from each of the P.I.s, as well as one from the RO (Responsible Official). They will be looking for compliance regarding CHPs and other OSHA rules, amongst other issues. There is no select agent work involving animal use at T.S.R.I. The results of the inspection, as well as recommendations to the T.S.R.I. Biosecurity Plan, will be discussed at the next IBC meeting.

Two IBC sub-committees have formed. One is a select agent publication screening committee (SAPS), which meets electronically. The other is a biosecurity action planning (BAP) committee, which is preparing for the upcoming CDC inspection. New restrictions involving the release of personal information in publications were discussed.

C. BSL-3 Report

A sub-committee of the IBC, consisting of Dr. _____, Dr. _____, Dr. [redacted] and [redacted] provided a report on the [redacted] BSL-3 facility. There have been improvements to the air handling system, the airlocks, and entryways. It has been proposed that the [redacted] facility be used only for the [redacted] lab's [redacted] work, which was previously taking place in the [redacted] P3 facility. The SIV work that is currently being performed in the [redacted] BSL-3 facility will need to be relocated. The [redacted] facility is not yet an approved BSL-3 facility. The [redacted] facility's supply and exhaust fans shut down last week. [redacted] along with Engineering, is looking into the matter. The [redacted] BSL-3 will be decontaminated with paraformaldehyde gas on November 24th, after the [redacted] work has been completed there, in order for the [redacted] lab to continue their work there. The committee voted to approve the recommendation that the [redacted] facility be used for [redacted] work only.

D. Anesthesia Machine Safety Issues

The anesthesia machines in both the animal biocontainment rooms and the regular rodent colonies, which use isofluorane, are shared and wheeled from room to room. They are shared to due their cost ($5000.00 per machine). Anesthesia procedures are not performed in fume hoods, as there are none available in biocontainment or nearby animal facilities. The concern of the committee is that cross-contamination could occur due to inconsistent changing of the delivery tubes, the failure to change out the clear trash bags, which are placed over the machine during each procedure, or other mishandling. Isofluorane is used instead of metaphane because metaphane is no longer produced in the United States, and has become too expensive. There is an existing campus stock of metaphane available at cost through [redacted] and [redacted] at ca. $500 per bottle. DAR provides training for the use of the anesthesia machines, but no one supervises the actual procedures. It was mentioned that the delivery tube is the most likely route of contamination. Each lab is required to purchase its own tubes. It was suggested that the training be improved, to emphasize the importance of not wearing dirty gloves, and of the necessity of changing bags and tubes. This may take the form of a video and will be included in the Biosafety on-line web training. A sub-committee of the IBC ([redacted] will oversee this process.

The meeting was adjourned at 3:45 p.m. The next meeting is scheduled for Wednesday, January 14, 2003 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
January 14, 2004

Present:

Donald E. Mosier, Ph.D., M.D., Chair
Joyce Joseph
Alana Althage
Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.
Mark Yeager, M.D., Ph.D
Richard Gulizia
Dennis Burton, Ph.D.
J. Lindsay Whitton, M.D., Ph.D
Juan Carlos de la Torre, Ph.D.
Ellen Trester

Absent:

Marta Perego, Ph.D
Thomas Northrup, Ph.D., J.D
Bruce Beutler, M.D.
Eric Johnson, Ph.D.

I. OLD BUSINESS

A. The minutes of the November 12, 2003 meeting were unanimously approved after some changes.

II. NEW BUSINESS

A. Review of Registration Documents.

1. #01-14-04-02 Dr. ____s protocol

An IBC member questioned whether the luciferase gene is being inserted into E. coli BL21 or H7; either project would be conducted at ABSL-2. The H7 strain was listed as the agent on the microbiological hazard registration form, and has not been modified. The Biosafety Office will clarify what the project entails.

2. #01-14-04-12 Dr. ____protocol

An IBC member mentioned that on the facility form for this protocol, both lab space and mouse containment rooms are listed. The PPE, decontamination, and other information listed on the facility form should apply to the lab. The facility information for animal containment is usually different from that of the lab; therefore that information should be listed on the animal form. The Biosafety Office will look into revising the registration forms to reflect this.

3. #01-14-04-07 Dr. [redacted]s protocol

   A cryostat is being used on this project; therefore the histology technicians should be listed as personnel, as they are being exposed to infected tissues. The technicians will be subject to the occupational medicine requirements for the project, specifically Hepatitis B titers or immunizations. The Biosafety Office will contact the P.I. regarding this issue.

4. #01-14-04-10 Dr. [redacted] protocol

   This project involves nude mice and will require the use of a room in containment. Dr. [redacted] has not yet been assigned space in the vivarium. The committee would like to confirm which space he intends to use for this project, and also for any projects involving the use of adenovirus vectors. The project should be BSL 2/3, and not BSL-2 as listed. The committee decided to defer approval of the project until the Biosafety Office obtains the information regarding the space to be used.

The registration documents were approved unanimously with the exception of the Schlaepfer application mentioned above.

B. Subcommittee on Anesthesia Machine Use and Training

At the November IBC meeting, the issue of unsafe handling of the anesthesia machines was discussed, and a subcommittee was appointed in order to create a training video. It was mentioned that the video might validate the use of what is not a safe process to begin with. The buildings that are primarily affected by this issue are [redacted].
The committee provided other suggestions, such as posting instructions on the sign out lists attached to the machines and requiring the user to sign and date the sheet prior to each use, designating certain machines to be used only with specific agents, and providing web site training in a manner similar to that of the biosafety training.

C. Assignment of ABSL-2 Space

The IACUC/DAR policy regarding the assignment of ABSL-2 space is being revised. A pdf form has been created, which categorizes agents into color-coded risk groups, and thus provides information about which pathogens can be used

within the same area. The form will also provide information regarding precautions for DAR staff. The means of routing the document, which needs to be reviewed by several separate departments and individuals, has yet to be decided. It was suggested that the form contain a section regarding the safety precautions necessary when working with the anesthesia machines.

D. CDC Inspection Follow-Up

The CDC inspection went well with only a few issues being mentioned. The [redacted] rooms have not yet been completed so the inspectors will be making a return visit in the future.

E. Other Business

1. An IBC member mentioned that the new form does not ask where the agent is being stored. The committee decided that storage information is only necessary when a select agent is being used.
2. Some members of the committee requested that a paper packet of the registrations be sent to them prior to the meeting, rather then reviewing the documents on line. [redacted] will send try to accommodate the members wishes.

The meeting was adjourned at 3:40 p.m. The next meeting is scheduled for Wednesday, March 10, 2003 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted]

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BIOSAFETY COMMITTEE
Meeting Minutes
March 10, 2004

Present:

Donald E. Mosier, Ph.D., M.D., Chair
Joyce Joseph
Alana Althage
Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.
Mark Yeager, M.D., Ph.D
Richard Gulizia
Thomas Northrup, Ph.D., J.D
J. Lindsay Whitton, M.D., Ph.D
Juan Carlos de la Torre, Ph.D.
Ellen Trester
Marta Perego, Ph.D

Absent:

Bruce Beutler, M.D.
Eric Johnson, Ph.D.
Dennis Burton, Ph.D.

I. OLD BUSINESS

A. The minutes of the January 14, 2004 meeting were unanimously approved. The occupational medicine requirements for histology technicians will be decided on a project-to-project basis, as most of the materials in the core lab are fixed and non-infectious. Any projects involving prions or human brain tissue will be subject to occupational medicine requirement review by the committee.

II. NEW BUSINESS

A. Review of Registration Documents.

1. #03-10-04-02 Dr. [redacted] protocol

The project involves transducing tumor cell lines, and employs the use of transgenic zebra fish. Other animals must be evaluated by the IBC.

Disposal methods are governed by the IACUC. The fish tank will provide biocontainment, and all procedures will be performed as cited in the IACUC protocol.

2. #03-10-04-04 Dr. [redacted] protocol

An IBC member mentioned that on a previous project, similar to this one, a condition of approval was that the injections take place within a certified BSC, due to a risk of aerosol transmission created by the hydrodynamic injection

process when live virus is used. The committee decided to make this a condition of approval for this project, as well.

3. #03-10-04-05 Dr [redacted]s protocol

   The SOP for this project, involving the use of Ectromelia-infected mice, was discussed. Lab personnel will change out and bag the cages, and then DAR staff will pick-up the bags for autoclaving at an appointed time.

4. #03-10-04-09 Dr. [redacted] protocol

   It was mentioned that although a centrifuge is being used, only use of bacteria cultures was checked off on the experimental procedure section of the facility form, and not tissue grinding. It was clarified that the project will not involve tissue grinding.

5. #03-10-04-13 Dr. [redacted], protocol

   The lab is obtaining frozen brain tissue samples from deceased Neimann-Pick disease diagnosed individuals. A tissue bank provided the tissue for this project. BSL-2 containment is required. The tissue will be treated with hexane, which extracts cholesterol out of the membrane. The tissue samples have an extremely low risk of containing human prions.

The registration documents were approved unanimously.

The meeting was adjourned at 3:15 p.m. The next meeting is scheduled for Wednesday, May 12, 2003 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted]

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BIOSAFETY COMMITTEE
Meeting Minutes
May 12, 2004

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Richard Gulizia
Joyce Joseph	Ellen Trester
Alana Althage	J. Lindsay Whitton, M.D., Ph.D
Juan Carlos de la Torre, Ph.D.	Marta Perego, Ph.D
Carolyn Keierleber, Ph.D.	Eric Johnson, Ph.D.

Absent:

Bruce Beutler, M.D.	Dennis Burton, Ph.D.	Thomas Northrup, Ph.D., J.D
Mark Yeager, M.D., Ph.D.	Beth Ford, D.V.M.	

I. OLD BUSINESS

A. The minutes of the March 10, 2004 meeting were unanimously approved.

II. NEW BUSINESS

A. Review of Registration Documents.

1. #05-12-04-10 Dr. ' , protocol

The project entails inserting retroviral vectors into human cell lines. The proposed animal work was deleted from the project, as it is not planned for some time. It came to the committee's attention that Dr. (as several retroviral constructs stored in . ab, although they are not currently in use. It was questioned as to whether or not they were registered.

2. #05-12-04-09 Dr. ' protocol

The formatting of the protocol's paper work came under question, as there are three different facility forms and MBH forms. This is due to the fact that the agents will be used in different locations and have different risks. A prolonged discussion on the merits of various registration methods ensued. We conclude that the paperwork was not as important as having trained responsible researchers. The Biosafety Office suggested conducting start-up meetings with labs prior to their starting work with a new agent. A training/mentoring program for new PIs was suggested.

3. # 05-12-04-08 Dr. [redacted] protocol

   A few committee members requested clarification as to what the project involved. The project is a continuation of the lab's previous registration for staphylococcus. A mutant is being generated, and then being sent on to a collaborator for insertion into mice. Staphylococcus is being grown in small amounts.

4. #05-10-04-11 Dr. [redacted] protocol

   The limit for the amount of staphylococcus used was questioned. The project is using 1 liter, maximum.

The registration documents were approved unanimously.

B. Florida protocol/relationship between IBCs-discussion

An IBC will not be created for TSRI Florida until Mecca is completed. Until then, the FAU IBC is in charge of biosafety for TSRI Florida, at both Boca Raton, and Jupiter. [redacted] will become an ad hoc member of the FAU IBC, in order to keep us involved with the approval process. Our IBC will provide a secondary review for project registrations at TSRI Florida. In order to complete these reviews, the committee will require first-hand knowledge of the physical set-up of lab and animal facilities so site visits will be necessary. Any discrepancies will be discussed via phone calls or videoconference. An IBC/EH&S member and a veterinarian will visit FAU prior to the TSRI committee's approval. They may attend the June FAU IBC meeting, and provide a site visit report to our committee. Secondary approval of [redacted] protocol will be deferred until the report is completed. FAU has not had [redacted] in use on its campus previously. The project involves isolating [redacted] sistant mice strains, and the mice will be kept in biocontainment. Pathogenic potential of mice scrapie to humans is unknown but transmission to humans has never been reported.

C. Animal Movement

Moving infected animals requires approval by EH&S and DAR. A template with an explanation of the process will

be posted on the EH&S website. DAR staff performs the actual moves.

The meeting was adjourned at 3:50 p.m. The next meeting is scheduled for Wednesday, July 14, 2004 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
July 15, 2004

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Mark Yeager, M.D., Ph.D.
Joyce Joseph	Ellen Trester
Alana Althage	J. Lindsay Whitton, M.D., Ph.D
Juan Carlos de la Torre, Ph.D.	Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.	Eric Johnson, Ph.D.
	Richard Gulizia

Absent:

Bruce Beutler, M.D. Dennis Burton, Ph.D. Thomas Northrup, Ph.D., J.D
Marta Perego, Ph.D

I. OLD BUSINESS

A. There was a discussion regarding the movement of animals from containment. It was confirmed that the movement of animals from one containment area to another will be monitored by DAR and EH&S. However, animals being moved out of containment entirely require IBC review. The minutes of the May 12, 2004 meeting were unanimously approved.

II. NEW BUSINESS

A. Review of Registration Documents.

1. #07-14-04-07 Dr. [redacted] protocol

It was mentioned that on the animal registration form for this project the room number needs to be changed from a regular animal room, R7, to IMM biocontainment, as it is a BSL-2/3 project.

2. #07-14-04-08 Dr. [redacted] protocol

It was questioned as to whether it was appropriate for work with flock house virus, listed at BSL-1, to be completed in a regular animal facility. The project involves propagating the virus in drosophila cells and injecting it into mice. SF9 cells, insect cells that are commonly used at TSRI, can contain other pathogens. There are no FDA approved drosophila cells available. The committee decided that the PI would need to screen the cell lines for pathogens (possibly using PCR) or otherwise establish that the material to be injected into animals was free of adventitious

virus. The Biosafety Office will contact the PI for more information regarding this host/vector system.

3. #07-14-04-09 Dr. [redacted]s protocol

   An IBC member asked whether using heat-killed Staphylococcus aureus in a regular animal room would be proper, as the agent is listed as BSL-2. The Sa will be boiled for two hours, which is considered sufficient time to kill the agent. The project is BSL-2 and ABSL-1.

4. #07-14-04-10 Dr. [redacted]s protocol

   An IBC member pointed out that the PI listed the agent, Pichinde virus, as non-pathogenic for humans. However, the BMBL states that it is pathogenic. Instances of infection in humans for this virus are very rare, according to local experts.

B. BSL-3 Facilities Update

The P2 level BSL-3 facility in [redacted] will be closed down for remodeling from August 2nd until approximately the first week in October. [redacted] will temporarily relocate their HIV and prion projects to the P1 level [redacted] BSL-3 facility. New features will include a more open lab design, an upgrade of the air handling system, and larger hoods. TSS will decontaminate the space prior to construction with paraformaldehyde gas. Freezers will be transported intact and locked to the [redacted]. It was suggested that all equipment remaining in the area be locked down, and that a formal recommissioning with posted signs take place upon completion of the remodel. A sub-committee of the IBC will inspect the facility upon completion, and the security access system will be updated

The meeting was adjourned at 3:30 p.m. The next meeting is scheduled for Wednesday, September 8, 2004 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
September 8, 2004

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Dennis Burton, Ph.D.
Ellen Trester	Thomas Northrup, Ph.D., J.D
Marta Perego, Ph.D.	J. Lindsay Whitton, M.D., Ph.D
Juan Carlos de la Torre, Ph.D.	Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.	Eric Johnson, Ph.D.
	Richard Gulizia

Absent:

Bruce Beutler, M.D.	Joyce Joseph
Alana Althage	Mark Yeager, M.D., Ph.D.

I. OLD BUSINESS

A. The minutes of the July 14th meeting were unanimously approved.

II. NEW BUSINESS

A. Insect and Rodent Control Program.

Dr. . _____ of the Department of Animal Resources spoke to the committee regarding the recent mite infestation in the l __ building, and the impacts such an incident could have on research being conducted here at TSRI. gave a very interesting summary of the work being done to eradicate the mites while protecting the animal workers and research animals. EH&S will speak with Environmental Services regarding any updates necessary to our Insect and Rodent Control Program.

B. Review of Registration Documents.

1. 09-08-04-02 Dr. (protocol
It was mentioned that the LD50 for this toxin is very high. The lab will be using the tomato bush virus to display the toxin. They will be using truncated toxin in the in vitro studies, and the live toxin will only be used in challenge studies. There was an error on form six of the registration, stating that the toxin was not pathogenic to animals. It was mentioned that Dr. _____ had stated that he would no longer be using animals for this project. The protocol was deferred until the use of animals could be clarified. If the project involves animal use, a specific protocol for injection would be warranted.

2. 09-08-04-06 Dr. [redacted] s protocol
   The protocol includes a novel method for the destruction of prions, and included a confidential manuscript and patent application. The [redacted] iat currently works with prions reviewed the documents. The decontamination method suggested for use is not as effective as bleach or autoclaving. Treated material was still lethal to mice after an incubation period. The PI wanted to use this method because it is less corrosive to metal. The project has not been started yet. The protocol was approved with the condition that standard methods of decontamination be used.

3. 09-08-04-03 Dr. [redacted] protocol
   This protocol will require a USDA permit for the use of scrapie at the [redacted] facility. There may also be an issue with the autoclave procedure, as the building has a small boiler. [redacted] is already approved for scrapie use. The PI will need to submit an animal housing form prior to obtaining space. The protocol was approved under the condition that a permit will be obtained if the project is to take place in the [redacted] acility.

The meeting was adjourned at 3:30 p.m. The next meeting is scheduled for Wednesday, November 10, 2004 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
November 10, 2004

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Mark Yeager, M.D., Ph.D.
Ellen Trester	Joyce Joseph
Marta Perego, Ph.D.	J. Lindsay Whitton, M.D., Ph.D
Juan Carlos de la Torre, Ph.D.	Beth Ford, D.V.M.
Carolyn Keierleber, Ph.D.	Richard Gulizia
	Alana Althage

Absent:

Bruce Beutler, M.D.	Dennis Burton, Ph.D.
Thomas Northrup, Ph.D., J.D.	Eric Johnson, Ph.D.

I. OLD BUSINESS

The minutes of the September 8th meeting will be redistributed to the IBC via email, following some edits.

II. NEW BUSINESS

A. Review of Registration Documents.

1. 11-10-04-03 Dr. [redacted] protocol

This project involves a toxic protein being expressed in plant algae. The toxin cannot enter human cells in its current form. Any modifications to the nucleic acid sequence encoding the protein, and any future antibody fusions, must be resubmitted to the IBC for review and discussion.

2. 11-10-04-08 Dr. [redacted] protocol

It was suggested that signage for the animal containment rooms be posted, regarding the risks of exposure to

It was mentioned that EH&S has a program for communicating biological, chemical, and radioactive risks The MBH form also contains a section that lists DAR occupational medicine requirements for each project.

The placards for the animal containment rooms are changed out every three months, with the list of pathogens in a particular room being updated.

Cage labels are also in use.

The BSL-3 facilities placarding protocol should be re-examined.

3. 11-10-04-09 Dr s protocol

   There was some discussion that ended in voting for approval.

4. 11-10-04-10 Dr_____) protocol

   This toxin is a select agent, but the amount being used is under the requirement for CDC registration. However, it does require the generation of a chemical hygiene plan and this is included in the document.

   There was some discussion of concentrations, and everything worked out OK when the calculations were done. The waste disposal section of the CHP needs to be altered to state that all waste will be picked up and disposed of by EH&S. Animal room CVN 134 was inadvertently listed and will be deleted from the form.

B. Anesthesia Machine Memo

   A memo regarding the cessation of the movement of anesthesia machines between animal containment rooms will be distributed to all investigators with registered ABSL-2 protocols. This change will be implemented by January 1, 2005. There was some discussion regarding 1) who would obtain use of the machines, 2) cleaning of machines, 3) where they can will be cleaned, and 4) avoiding any potential conflicts.

The meeting was adjourned at 3:20 p.m. The next meeting is scheduled for Wednesday, January 12, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by: .....

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BIOSAFETY COMMITTEE
Meeting Minutes
January 12, 2005

Present:
Donald E. Mosier, Ph.D., M.D., Chair
Eric Johnson, Ph.D.
Marta Perego, Ph.D.
Juan Carlos de la Torre, Ph.D.
Dennis Burton, Ph.D.
Joyce Joseph
Alana Althage
Thomas Northrup, Ph.D., J.D
Richard Gulizia

Absent:
Bruce Beutler, M.D.
Carolyn Keierleber, Ph.D.
Ellen Trester
Mark Yeager, M.D., Ph.D.
Beth Ford, D.V.M.
J. Lindsay Whitton, M.D., Ph.D.

I. OLD BUSINESS

A. The committee was brought up to date regarding the use of anesthesia machines here at TSRI. The memo regarding the cessation of movement of machines between rooms was distributed to the relevant PIs. As of yet, no new machines have been purchased. The ..... building would like to share their machines among different labs, and a protocol is being developed to facilitate this process. The policy on anesthesia machine usage is a work in progress, and issues will continue to be addressed as they come about.

B. The minutes of the November 10th meeting were unanimously approved.

II. NEW BUSINESS

A. Review of Registration Documents.

1. 01-12-05-03 Dr. _____'s protocol

There was some question as to how the virus would be applied to the grid, and it was mentioned that this process needed to take place within a self-contained environment. The pipette will be loaded within a biosafety cabinet, and then carried to the vitrification device in a closed, leak-proof container.

2. 01-12-05-06 Dr. _____'s protocol

This project involves the injection of a human pathogen into mice, and therefore the biosafety

level and animal biosafety level were both changed from level 1 to level 2. Also, the space listed on the animal form cannot be used for this project. An animal space assignment form will need to be submitted. The MBH form for this project was reviewed separately, and is on file. In the future, preexisting MBH registrations will be noted on the registration documents that are submitted to the committee. The protocol was approved contingent upon the changes mentioned above.

3. 01-12-05-08 Dr. [redacted] protocol

It was questioned as to whether the bulk culture of salmonella choleraesuis will be tested for the number of organisms present prior to administration to mice. EH&S will contact the lab to determine this.

B. SARS protocols and CA DHS

The CDC requested that the CA DHS obtain information regarding SARS work at TSRI. The SOP for Dr. Buchmeier's project was forwarded to them for review. Upon recommendation from the CA DHS, a virus inventory system was implemented.

C. Infectious Agent Work During Pregnancy

The committee discussed TSRI's policy for work with infectious agents during pregnancy. There was a discussion regarding the extent of responsibility of the PI.

The meeting was adjourned at 3:10 p.m. The next meeting is scheduled for Wednesday, March 9, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted]

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BIOSAFETY COMMITTEE
Meeting Minutes
March 9, 2005

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Carolyn Keierleber, Ph.D.
Eric Johnson, Ph.D.	Joyce Joseph
J. Lindsay Whitton, M.D., Ph.D.	Alana Althage
Juan Carlos de la Torre, Ph.D.	Beth Ford, D.V.M.
Dennis Burton, Ph.D.	Richard Gulizia
Mark Yeager, M.D., Ph.D.	Ellen Trester

Absent:

Bruce Beutler, M.D.	Marta Perego, Ph.D.
Thomas Northrup, Ph.D., J.D	

I. OLD BUSINESS

A. The minutes of the January 12th meeting were unanimously approved.

II. NEW BUSINESS

A. Review of Registration Documents.

1. 03-09-05-01 Dr. ' _____ . protocol

This project involves the use of lentivirus in the transduction of mouse stem cells. It was provisionally approved with the condition that animal experiments be conducted in ABSL-2 space, which segregates the mice from other immunodeficient strains, and has a biosafety cabinet for procedures and changing.

2. 03-09-05-08 Dr. _____ protocol

This protocol was not provisionally approved. It was recommended that this pathogen be handled at BSL-2, due to the risk to immunosuppressed individuals. The post doc in the lab had previously used it at BSL-1 at another facility. The pathogen was listed at BSL-1 in the pre-AIDS era. The project involves growing up 10ml of *Candida albicans* and *Candida glabrata*. There is no biosafety cabinet available in the lab. The genomic DNA, which will still enable the

viewing of the proteins, may be obtained, since the lab does not want to work at the BSL-2 level. The committee concurred that the pathogen should be BSL-2.

3. 03-09-05-09 Dr. _____ protocol

This protocol was not provisionally approved. The _____ lab plans on growing the Hepatitis B virus, but does not have experience working with this pathogen. The committee would like to see more project details, including what drugs will be introduced into the cell line, and what the target is. EH&S will contact the post doc involved with the project.

4. 03-09-05-13 Dr. _____ protocol

This project involves the use of *Trichinella spiralis*, a worm parasite, which is a human pathogen. The parasite will be fed orally into a mouse model, and will then be shed in the stool for a two-three day period. The infection then becomes systemic. The pathogen has a fecal-oral transmission route. This project will require special handling due to the risk to other mice in the vicinity. Recommending that all of the work be done in a BSC would limit the availability of space in which the project could be performed. The project will also involve necropsy of the mice to remove infected tissue, which would be completed in the lab space where a BSC is available. The larvae and the worms will be introduced at different times and into different animals. The larvae are environmentally stable. The lab had previously performed the cage changing duties themselves at another facility. The committee decided to approve the protocol with the condition that the PI submits a SOP for the cage changing protocol.

B. Occupational Medicine- HCV Project

The _____ lab has recently developed a cell line that expresses the Hepatitis C virus. The PI has requested that a program be set up to make titers

available to the 3-5 personnel working on the project quarterly, and to the whole lab annually. A titer for Hepatitis C antibodies, which determines past exposure, and one for RNA, which determines active infection, will be completed. The project will take place in a dedicated tissue culture room. EH&S has completed an SOP for the administration of the titers.

C. MBB BSL-3 Facility Inspection

A subcommittee of the IBC recently inspected the renovated BSL-3 laboratories on the P2 level of MB. Minor repairs that were required have been completed, and the facility is up and running.

D. SARS

EH&S received a letter from the state epidemiologist regarding the work that is taking place at TSRI. They sited several safety precautions that would be necessary to follow, and requested an inventory.

E. Updating of Registration Forms & Web Training

will be updating the biosafety registration forms in the near future. If you have any suggestions please email him. will also be updating the web-training program. A sub-committee was appointed to assist with this process.

The meeting was adjourned at 3:15 p.m. The next meeting is scheduled for Wednesday, May 11, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by

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BIOSAFETY COMMITTEE
Meeting Minutes
May 11, 2005

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Carolyn Keierleber, Ph.D.
Joyce Joseph	Ellen Trester
J. Lindsay Whitton, M.D., Ph.D.	Alana Althage
Juan Carlos de la Torre, Ph.D.	Beth Ford, D.V.M.
Richard Gulizia	Thomas Northrup, Ph.D., J.D

Absent:

Bruce Beutler, M.D.	Marta Perego, Ph.D.	Dennis Burton, Ph.D.
Eric Johnson, Ph.D.	Mark Yeager, M.D., Ph.D.	

I. OLD BUSINESS

A. The minutes of the March 9th meeting were unanimously approved.

II. NEW BUSINESS

A. Review of Registration Documents.

1. 05-11-05-07 Dr. [redacted] protocol

Regarding the use of animals for this registration, it was mentioned that the personnel listed on the project have no experience with the hydrodynamic injection technique. It was decided that proficiency regarding this technique must be demonstrated before approval for animal use is granted. An IBC member, who is skilled at hydrodynamic injections, agreed to supervise the training of the [redacted] personnel. After proficiency of the technique has been documented, Dr. [redacted] may resubmit the animal portion of this application.

2. 09-08-04-02 Dr. [redacted] is protocol

This submission was an amendment to an existing registration. Requests for additional information regarding the LD_{50} for humans, volume and concentration amounts for the animal challenge studies were needed prior to the start of work on

the project. In addition, the personnel from the _____ lab who will be injecting the animals should be added to the application. _____ stated that an amendment to add the personnel had already been received by the biosafety office. There was also a request to verify that the Chemical Hygiene Plan (CHP) regarding this project covers the animal work. The biosafety office will follow up with the information required.

3. 03-13-02SA-01 Dr. _____ protocol

The committee reviewed a set of registration forms regarding Dr. _____ s project #03-13-02SA-01. These documents describe a project using botulinum toxin, and were created to match a CHP that was already reviewed and approved by the committee. The documents were created to allow the biosafety office to track the project in similar fashion as others that are registered. It was also stated that the CDC had reviewed the project and inspected the laboratory where the work will take place. After the review and inspection the CDC approved both the space and protocols.

All of the protocols were unanimously approved with the exception of the animal work for the _____ protocol #05-11-05-07 mentioned above.

B. IBC Review of Scripps Florida Applications

The current dual review process was described as slow and cumbersome. The use of the FAU forms does not capture sufficient information for making informed decisions. The committee discussed several options to improve the review process.

The formation of a subcommittee to review Scripps Florida applications was discussed. This subcommittee would have the delegated authority to approve Scripps Florida protocols by a vote from the full IBC. This option was rejected by the IBC, as it did not fix any of the inherent problems.

A second option was to add Scripps Florida faculty members to the TSRI IBC, and change the registration documents to those used at TSRI. This option failed to get support, as there was concern over the lack of knowledge about laboratory layout, and expertise between Scripps Florida faculty and TSRI.

The third option discussed was to encourage the Scripps Florida faculty to form their own IBC. Members of the TSRI IBC and biosafety office expressed a willingness to help with the formation of an independent committee at Scripps Florida. This option gained unanimous consent from the IBC. A memo will be generated by [redacted] regarding these discussions and the suggested course of action and will be sent to Dr. [redacted]

The meeting was adjourned at 3:40 p.m. The next meeting is scheduled for Wednesday, July 13, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
July 13, 2005

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Carolyn Keierleber, Ph.D.
Joyce Joseph	Marta Perego, Ph.D.
J. Lindsay Whitton, M.D., Ph.D.	Alana Althage
Juan Carlos de la Torre, Ph.D.	Mark Yeager, M.D., Ph.D.
Richard Gulizia	

Absent:

Bruce Beutler, M.D.	Beth Ford, D.V.M.	Dennis Burton, Ph.D.
Eric Johnson, Ph.D.	Ellen Trester	Thomas Northrup, Ph.D., J.D.

I. OLD BUSINESS

A. The minutes of the May 11th meeting were unanimously approved.

B. The IBC Chair generated a memo to , regarding the committee's recommendations for an independent IBC for Scripps Florida.

II. NEW BUSINESS

A. Review of Registration Documents.

1. 07-13-05-05 Dr. protocol

An IBC member mentioned that the RDNA form had animal cell lines COS7 and MDCK listed under the section for human cell lines. The Biosafety Office will correct the form. The IBC Chair had recommended testing for replication competent retroviruses for this project, which involves insertion of human oncogenes into retroviral vectors capable of infecting humans. There is a safety concern regarding the possibility of insertion into a cell line that may have already been transduced, as different labs often share cell lines.

2. 07-13-05-07 Dr. protocol

There was a question as to whether self-inactivating SIN vectors should be classified as BSL-2 or BSL-2/3. These vectors can recombine and mutate when inserted into mice. If the vector is not inserted into an infected cell line or animal, then no helper is available, and it cannot recombine. This project involves inserting plasmids into 293T cells. The lab is concentrating the virus and injecting it into mice. The use of the VSV-G envelope determines that the project should be BSL-2/3. The animal biosafety level was also changed from ABSL-2 to ABSL-2/3 for the use of Hepatitis B transgenic mice.

3. 07-13-05-06 Dr. [redacted] protocol

   It was mentioned that murine retroviruses, while not being human pathogens, could still recombine in a similar manner to lentiviral vectors. Amphotropic envelopes require registration at BSL-2/3, but ecotropic envelopes are BSL-2.

4. 07-13-05-08 Dr. [redacted] protocol

   An IBC committee member mentioned that the MBH form for Coxsackie virus mistakenly states that it is exclusively a human pathogen. Coxsackie virus is also an animal pathogen. The Biosafety Office will correct the form.

5. 07-13-05-10 Dr. [redacted] protocol

   It was mentioned that this project should be classified as BSL-2/3 and ABSL-2/3. The PI had already agreed to this change, but the MBH form needs to be altered to reflect the change.

All of the protocols were unanimously approved with the changes mentioned above.

B. Project

The Biosafety Office has submitted an amendment to the CDC in order for the [redacted] lab to be permitted to use botulinin toxin in [redacted] and [redacted] which are located outside of the already approved

location in the BSL-3 facility. A CHP was required for the experiment, and less than 0.5 mg will be used. The amendment is pending CDC approval. The IBC approved this project, contingent upon the CDC approval.

C. National Science Advisory Board for Biosecurity

The members of NSABB were appointed. This committee may make decisions regarding new tasks and guidelines in relation to IBC operations and activities.

The meeting was adjourned at 3:10 p.m. The next meeting is scheduled for Wednesday, September 14, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by [redacted].

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BIOSAFETY COMMITTEE
Meeting Minutes
September 14, 2005

Present:

Donald E. Mosier, Ph.D., M.D., Chair
Joyce Joseph
J. Lindsay Whitton, M.D., Ph.D.
Juan Carlos de la Torre, Ph.D.
Richard Gulizia
Thomas Northrup, Ph.D., J.D.
Carolyn Keierleber, Ph.D.
Marta Perego, Ph.D.
Alana Althage
Beth Ford, D.V.M
Ellen Trester

Absent:

Bruce Beutler, M.D.
Mark Yeager, M.D., Ph.D.
Dennis Burton, Ph.D.
Eric Johnson, Ph.D.

I. OLD BUSINESS

A. The minutes of the July 13th meeting were unanimously approved.

B. An IBC member questioned whether the lab had completed the recommended testing for replication competent retroviruses for protocol #07-13-05-05, which was reviewed at the July meeting. The Biosafety Office will follow-up with this issue by contacting the post doc who will be completing the experiments. It was mentioned that there is a cell line available through ATCC that is useful in testing for reconstitution in viruses, and it may prove to be a valuable resource.

II. NEW BUSINESS

A. Review of Registration Documents.

1. 09-14-05-01 Dr. protocol

The protocol was provisionally approved with the condition that a CDC import permit was obtained prior to the start of the project. The biosafety office has received the import permit for the Oldstone slides. This project involves the use of JCD (Jakob Creutzfeldt Disease) tissue, which is presumed infectious. The committee approved the protocol with the condition that a procedure addressing disposal of slides, and indicating what should be done in case of an accidental cut while processing slides, is developed.

2. 09-14-05-06 Dr. ____ protocol

   There was a discussion regarding the injection description for this project. Two IBC members offered to contact the lab for clarification on the injection technique.

3. 09-14-05-09 Dr. ____ protocol

   An IBC member questioned whether there was a procedure written for the intra-nasal injection. The ____ lab, of which Dr. ____ is a member, has one written. It was mentioned that intra-nasal injections are commonly performed on mice and ferrets using the influenza virus. There was a discussion regarding the possibility of the mice shedding vaccinia virus. No high titers of virus are shed in the urine/stool. The committee recommended that the experiment be completed inside a BSC to reduce the risk of aerosol transmission.

4. 09-14-05-10 Dr. ____ protocol

   It was suggested that masks, in addition to other PPE, be worn while working with this toxin, as it is in powder form, and a very small amount can cause symptoms.

5. Addendum to 05-11-05-06 Dr. ____ protocol

   This project involves the hydrodynamic injection of HBV plasmids into mice. The post doc performing the injections has been trained for this procedure by an IBC member, and has extensive previous knowledge of IV injections.

All of the protocols were unanimously approved with the changes mentioned above.

B. Select Agent Inspection Report

The CDC performed an inspection of the TSRI select agent program on August 31st and September 1st. We will receive a report regarding the

inspection in about six weeks. Some of the issues that need to be addressed include cloth chairs being used in the labs, providing commissioning reports for the lab facilities, and having a log of lab visitors in place that records any person entering the lab, even if select agent materials are not in use at the time. We were able to provide the visitor log for the BSL-3 facilities, as they require key card access.

The meeting was adjourned at 3:45 p.m. The next meeting is scheduled for Wednesday, November 9, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by .

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BIOSAFETY COMMITTEE
Meeting Minutes
November 9, 2005

Present:

Donald E. Mosier, Ph.D., M.D., Chair
Joyce Joseph
Alana Althage
Juan Carlos de la Torre, Ph.D.
Richard Gulizia
Thomas Northrup, Ph.D., J.D.
Carolyn Keierleber, Ph.D.
Marta Perego, Ph.D.
Eric Johnson, Ph.D.
Beth Ford, D.V.M
Ellen Trester

Absent:

Bruce Beutler, M.D.
Mark Yeager, M.D., Ph.D.
Dennis Burton, Ph.D.
J. Lindsay Whitton, M.D., Ph.D.

I. OLD BUSINESS

A. The minutes of the September 14h meeting were unanimously approved.

II. NEW BUSINESS

A. Review of Registration Documents.

1. 11-09-05-02 Dr. [illegible] / protocol

It was mentioned that the biosafety level for this protocol should be BSL-2, not BSL-1, as the agent being used is kanamycin-resistant *Escherichia coli*. The protocol will be approved with the change in biosafety level.

2. 11-09-05-04 Dr. [illegible] protocol

This project involves the receipt of murine brain tissue from France, which will require a MTA and USDA permit. The USDA permit has already been obtained. The project will require an IACUC protocol only if there exists a true collaboration between the lab and the facility in France.

3. Dr. [illegible] protocols

These protocols involve the injection of antibiotic-resistant bacterial strains into mice.

The occupational medicine physician created a guidance document citing antibiotics that may be used to treat an exposure. Several options were listed so drug allergies could be taken into account. An instruction sheet providing lab employees with information on what to do following an exposure event was also created. The Biosafety Office will contact the lab regarding the protocol for exposure events, and will contact Sharp to assure that all of the occupational medicine physicians are aware of the protocol. The committee expressed some concern regarding whether or not lab personnel would be able to distinguish between the various bacteria if an exposure was to occur. The vivariums are now equipped with cage labels that list the agent, which may prove helpful.

4. 11-09-05-10 Dr. _____ protocol

It was questioned as to whether any special instructions needed to be given to the animal care staff for this project. The lab will inject anthrax toxin into mice. The toxin is not infectious, and is not shed. The main safety issue is in regard to self-inoculation.

5. 11-09-05-06 Dr. _____ protocol

This protocol involves the inoculation of mice with *Plasmodium yoelii*, which is a mouse strain. Dewey Pest Control has been contacted regarding options for mosquito traps for the vivarium, which will allow a vector surveillance plan to go into effect. If necessary, a vector control plan will be created. It was requested that the PI state that no blood feeding will occur.

All of the protocols were unanimously approved with the changes mentioned above.

B. Prion Update

The IBC Chair gave a brief talk in regard to a study which documented the transmission of Chronic Wasting Disease (CWD) prions from deer and elk brains into squirrel monkeys via direct inoculation to the brain. This resulted in

progressive neurodegenerative disease. The study indicates the potential of transmission to primates, and possible human infection. The Oldstone lab is using transgenic mice with CWD at BSL-2 level practices. Since the agent is not aerosol transmitted, the biosafety level should remain the same. However, the practices should reflect those used when working with BSE.

C. ABSA Conference Highlights

The Director of Environmental Health & Safety gave a brief recap of events at the ABSA (American Biological Safety Association) conference in Vancouver.

D. 1918 Influenza Virus

The IBC Chair discussed a delay in publication of an article about the 1918 influenza virus pandemic. The virus, which had an unusually high mortality rate among young adults, had been reconstructed via molecular clones. Publication was held up by the Department of Health and Human Services, in regard to whether or not information in the article should be considered "classified". The NIH and CDC had already reviewed the article. In the future, the National Science Advisory Board for Biosecurity, which determines policy for "dual use" publications, will delegate the responsibility of determining whether or not a publication may divulge sensitive biosecurity information to the IBCs. There is currently no law governing this type of review, in relation to publication.

The meeting was adjourned at 3:30 p.m. The next meeting is scheduled for Wednesday, January 11, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by I

BIOSAFETY COMMITTEE
Meeting Minutes
January 11, 2006

Present:

Donald E. Mosier, Ph.D., M.D., Chair	Carolyn Keierleber, Ph.D.
J. Lindsay Whitton, M.D., Ph.D.	Marta Perego, Ph.D.
Alana Althage	Mark Yeager, M.D., Ph.D.
Juan Carlos de la Torre, Ph.D.	Beth Ford, D.V.M
Richard Gulizia	Ellen Trester

Absent:

Bruce Beutler, M.D.	Dennis Burton, Ph.D.
Eric Johnson, Ph.D.	Joyce Joseph
Thomas Northrup, Ph.D., J.D.	

I. OLD BUSINESS

A. The minutes of the November 9th meeting were unanimously approved, with the condition that they be updated to reflect that Dr. ¶ protocol (11-09-05-08) involving *Bacillus subtilis* and *Bacillus megaterium* is a BSL-1, and not BSL-2, project.

II. NEW BUSINESS

A. Action Item List

A motion was made, and unanimously approved, to generate an action items list for each IBC meeting. The list will contain any tasks that required follow-up at the meeting, and will be assigned to the appropriate individual for resolution. The Biosafety Officer will be responsible for creating the list and reporting on the status of the items at the next IBC meeting.

B. Review of Registration Documents

1. 01-11-06-02 Dr.' ____protocol

It was questioned as to whether the animal work for this project should be completed in an ordinary animal room. The project involves the use of Staphylococcal Enterotoxin B (SEB), which is not infectious, and is not shed by the animals. However, there is the concern of the toxin being absorbed through the skin by personnel if there was a spill. The toxin is

considered a select agent, but the amount being used is exempt from the CDC registration requirement. The CHP for this project needs to be updated to address the animal work portions of the project.

2. 01-11-06-04 Dr. ___ ; protocol

   On the animal registration form for this project, the injection method is described as intratracheal in one section, and then intraperitoneal and intramuscular in another section. The Biosafety Office will contact the lab to clarify which procedure will be used.

3. 01-11-06-05 Dr. _____ protocol

   On the RDNA registration form for this project, some human cell lines are listed under the animal cell line section and vice versa. The form needs to be updated to correct this.

4. Addendum to 11-08-00M-05 Dr. protocol

   The work for this project needs to take place in an ABSL-2 approved space, which will be assigned by DAR, and not in the room noted on the animal registration form, Room 17. It was recommended that the Biosafety Office add a statement to the bottom of all of the registration forms, indicating that the IBC must be contacted prior to a lab initiating animal work for a project.

All of the protocols were unanimously approved with the changes mentioned above.

C. Discussion regarding

The IBC had a discussion regarding its role in the protection of workers who wish to use infectious disease agents in research. The administration is concerned that limiting access to infectious agents may not be appropriate in light of the 1991 Johnson Controls Supreme Court decision.

[redacted], has offered to provide more information on current labor practices March IBC meeting.

The meeting was adjourned at 3:20 p.m. The next meeting is scheduled for Wednesday, March 8, 2005 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by I

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BIOSAFETY COMMITTEE
Meeting Minutes
March 8, 2006

Present:

Donald E. Mosier, Ph.D., M.D., Chair
J. Lindsay Whitton, M.D., Ph.D.
Joyce Joseph
Juan Carlos de la Torre, Ph.D.
Richard Gulizia
Carolyn Keierleber, Ph.D.
Marta Perego, Ph.D.
Thomas Northrup, Ph.D., J.D.
Beth Ford, D.V.M

Absent:

Bruce Beutler, M.D.
Eric Johnson, Ph.D.
Ellen Trester
Dennis Burton, Ph.D.
Mark Yeager, M.D., Ph.D.
Alana Althage

I. OLD BUSINESS

A. The minutes of the January 11th meeting were unanimously approved, after a brief discussion regarding SEB use. The IBC voted to allow SEB use in normal animal rooms since the protein is metabolized and does not accumulate in animal bedding.

II. NEW BUSINESS

A. Introduction of

; Biosafety Coordinator, was introduced to the committee.

B. Review of Registration Documents

1. 03-08-06-01 Dr. s protocol

The members discussed the rationale for using this agent. Listeria will target macrophages and deliver the ovalbumin gene to the appropriate tissue being studied.

2. 03-08-06-09 Dr. _____ protocol

The committee asked where the Herpes Simplex vector was being obtained.

All of the protocols were unanimously approved.

C. IBC/IACUC Meeting

One of the committee members who had attended the IBC/IACUC meeting described the talks given there. Several IBC members had attended at least one day of the meeting.

D. Retrovirus Discussion

The IBC Chair asked for a brief discussion regarding testing for replication competent retroviruses. Some institutions require this while others do not. The committee decided to find out the cost of using the UCSD CFAR core laboratory and to evaluate the cost of using their service. It was decided that an IBC policy regarding this would be put together and reviewed at the next meeting.

E. Discussion

The IBC Chair reviewed the situation regarding the policy for employees with primary, secondary, or elated immune deficiency. There was a meeting on 1/18/06 with a labor attorney who advised the IBC members regarding this issue. A subcommittee of IBC members put together a list of agents that are high risk and moderate risk to these employees. This subject is still under discussion, but increased training of new employees to ensure they are aware of these risks will be a part of the new policy statement.

F. Security Issues

There was a brief discussion on security issues with regard to animal facilities.

G. New Committee Member

The IBC Chair recommended a possible new member of the IBC to the Vice President of Research Affairs.

The meeting was adjourned at 3:30 p.m. The next meeting is scheduled for Wednesday, May 10, 2006 at 2:30 p.m. in the Tennis Room of the Faculty Club, Building 3300, and will be chaired by L

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