

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

May 22, 2003

9:00 am to 10:30am

C-124 Conference Room

Engineering Research Complex

In attendance:

John Gerlach
Rebecca Grumet
Patty Weber
Bob Silva
Patrick Venta
George Anderson
Steve Bolin
Robin Mecklem
Jamie Sue Willard
Lisa Ann Maul
Kevin Eisenbeis

Researchers in attendance: None

Absent: Michael Kron, Susan Ewart, Marco Scarpetta, Ned Walker, Dave Douches

Call to order: John Gerlach

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting:

Minutes from the April 2003 meeting were discussed and approved contingent upon amendment of quanine to guanine.

Old Business: The VanAndel compilation document is still under review pending responses, corrections and signatures from the Principal Investigators.

New Business: The subject of document control was raised for the protection of sensitive research issues and how to maintain privacy for our research community. Robin Mecklem proposed that all registration documents be returned to the ORCBS for shredding/or be shredded by the reviewer and that only the comment sheets be maintained with the original document to be filed at the ORCBS.

IBC # 723 (Rebecca Grumet): This project involves the field trial testing of transgenic cucumber plants pending approval of the IBC and USDA. The genes were inserted many generations ago. The committee approved the registration as written.

IBC # 724 (Lucy Lee – ADOL): There were several form-related inconsistencies that needed to be addressed. Additionally, there are safety-related items that need to be clarified. The ORCBS Biosafety Staff will meet with the Principal Investigator to address these issues and fine tune the proposed registration document. The committee placed a contingent approval of the registration based on the corrections made by the researcher with a final review by John Gerlach and Robin Mecklem.

IBC # 726 (Robert Silva – ADOL): The committee approved the registration, but suggested that the researcher make it clear what fraction of the source genome is being used.

Lisa Ann Maul presented a summary document to review the accomplishments and trends of the IBC from 2001 to 2002. Overall, the number of registrations and departments who registered projects did not change significantly.

This lack of change raised a question regarding the authority of the IBC (i.e. What does the IBC do if people are working with recombinant DNA and not registering?). Kevin Eisenbeis will research the question of the IBC's responsibilities and authority.

Robin Mecklem discussed the inspection reports and how they would soon be distributed to the Department Chairs and Safety Representatives to raise awareness of laboratory safety and inspections. She also noted the inspection of the proposed Zeikus lab space did not find the space appropriate for BSL 2 work proposed under IBC # 714. Zeikus lab representatives were given 30 days to implement BSL 2 containment practices with a follow-up inspection pending.

The next IBC meeting was scheduled for June 18, 2003 from 9 to 10:30am.

The motion was made and seconded to adjourn.

Prepared by:
Jamie Sue Willard, Ph.D
Biological Industrial Hygienist
The Office of Radiation, Chemical and Biological Safety

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

June 18, 2003

9:00 am to 10:30am

C-103 Conference Room

Engineering Research Complex

In attendance:

Ned Walker
John Gerlach
Rebecca Grumet
Patty Weber
Bob Silva
Patrick Venta
George Anderson
Steve Bolin
Marco Scarpetta
Robin Mecklem
Jamie Sue Willard
Alissa Wesche
Ellen Armentrout

Researchers in attendance: None

Absent: Michael Kron, Susan Ewart, Dave Douches

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting:

Minutes from the May 2003 meeting were discussed and approved.

Discussion of the agenda for current meeting: Agenda discussed and approved with the addition of Dr. Zhang's registration review.

Old Business: A discussion briefly ensued in the May meeting regarding the IBC membership and voting policies. The discussion continued in the current meeting and several issues were covered again including: 1) the change of status of Dr. Micheal Kron from an active member of the IBC to an ad hoc member to be drawn in when registrations involving human infectious disease issues were being reviewed, 2) the addition of the BSO as a voting member of the IBC, and 3) the possible addition of Dr. John Ohlrogge to the IBC on an ad hoc basis. Although it was agreed that Dr. David Wright should make the final decision regarding these issues, the committee voted and was in consensus to all the issues discussed. It was also noted by a committee member that another community representative should be selected to ensure that review voting could occur. The process has been underway for some time to locate an individual for this

position. Ideal candidates are individuals with no affiliation to MSU but have some connection to community service (i.e. clergy, retired school teacher, etc.).

New Business: Four registrations were reviewed and votes taken. Results are as follows:

IBC # 727 (Aly Fadly – ADOL): The committee voted for contingent approval of the project. The cell information was complete, but the research process was too vague. The committee requested an expanded project summary to include the goals and objectives of the study and a brief explanation of the experimental design.

IBC # 729 (David Douches): Contingent approval was placed on this project. The contingencies included the amendment of the review category from III-E to III-D (transgenic plant use), proof of notification from the USDA/APHIS and explanations of the DES and RB abbreviations.

IBC # 730 (Catherine Ernst): The committee approved the registration for the exempt status.

IBC # 731 (Huanmin Zhang ADOL): The committee approved the registration form as written; however, the ORCBS Biosafety staff will request a project summary for Dr. Zhang's permanent file.

A brief update of the web-based registration construction was provided by the BSO. Establishing entry codes and passwords was still problematic. Risk assessments are also required in the registrations. The BSO will work with the computer technologists and determine if the information from the registration can be pooled in a specific manner to provide the risk assessment from the current registration. Thus, Principal Investigators will not be required to enter more information.

Document control in the registration review process was discussed again with a draft of the policy provided by the BSO. The committee agreed to the policies provided with the understanding that the General Counsel will assist with the legal language of the document.

The next IBC meeting was scheduled for July 31, 2003 from 9 to 10:30am at ADOL.

The motion was made and seconded to adjourn.

Prepared by:

Jamie Sue Willard, Ph.D

Biological Industrial Hygienist

The Office of Radiation, Chemical and Biological Safety

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

July 31, 2003

9:00 am to 10:30am

Conference Room

Avian Disease and Oncology Laboratory

In attendance:

Ned Walker
John Gerlach
Susan Ewart
Bob Silva
Patrick Venta
George Anderson
Steve Bolin
Robin Mecklem
Jamie Sue Willard
Alissa Wesche
Lisa Ann Romero
Ellen Armentrout
Kevin Eisenbeis

Researchers in attendance: None

Absent: Michael Kron, Rebecca Grumet, Dave Douches, Marco Scarpetta, Patty Weber

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting:

Minutes from the June 2003 meeting were discussed and approved.

Old Business: The voting policies and membership issues that were approved during the June meeting, but referred on for Dr. David Wright's review, were opened for discussion again after the Biosafety Officer conferred with Dr. Wright. He agreed that Dr. Michael Kron should be a member of the Institutional Biosafety Committee on an ad hoc basis. In the June meeting, it was decided that the vacancy created by this action should be filled with an individual with plant expertise. Dr. John Ohlrogge was suggested. The Biosafety Officer contacted Dr. Ohlrogge, but he was unable to commit the time to the position. At the current meeting, the Biosafety Officer mentioned Dr. Jan Byrne, who is the plant pathologist for the Center for Integrated Plant Systems at MSU. The committee agreed her plant pathogen expertise would be beneficial to the committee. The Biosafety Officer will contact her before the next meeting.

Dr. Wright requested that the General Counsel's office review the proposed role of the BSO as a voting member of the IBC to determine if this action would raise conflict of interest concerns. Some discussion ensued regarding this issue; however, the committee and the General Counsel representative were in agreement that predictable conflicts were not apparent. If by chance a conflict does rise, the decision was made to have the Biosafety Officer refrain from voting on the conflicting issue.

The continuing need for another community representative was discussed. A member of the committee suggested an individual who has potential for the position. The Biosafety Officer will contact the potential member before the next meeting.

New Business: Three registrations were reviewed and votes taken. Results are as follows:

IBC #: 732 (Christoph Benning): The committee approved the registration as written. Plant containment questions were addressed as part of the general discussion of the registration. The ORCBS Biosafety Staff will conduct further investigations into plant containment procedures for the committee's future reference.

IBC IBC # 735 (John Ohlrogge): The committee approved the registration as written. Seed containment issues were addressed in the general discussion. The ORCBS Biosafety Staff will also conduct further investigations into this subject and provide the committee with reference information at the next meeting.

IBC # 725 (Simon Petersen-Jones): The committee voted for contingent approval of the renewal registration. The contingencies are as follows 1) PI must provide information regarding the packaging system to verify that the system would not allow the generation of a replicative virus, 2) PI must provide validation of IBC approval/review from the institutions where the viral vectors are produced. The committee also approved the change from animal biosafety level 2 to 1. The ORCBS Biosafety Staff will inspect the research facilities where the vectors are prepared for administration to the animals. After these items have been addressed and reviewed by the IBC Chair or Vice Chair, final approval will be granted.

The next IBC meeting was scheduled for August 27, 2003 from 9 to 10:30am in the ORCBS conference room.

The motion was made and seconded to adjourn.

Prepared by:
Jamie Sue Willard, Ph.D
Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

August 27, 2003

9:00 am to 10:30am

ORCBS Training Room

In attendance:

Ned Walker
John Gerlach
Susan Ewart
Bob Silva
Patrick Venta
George Anderson
Rebecca Grumet
Patty Weber
Jan Byrne
Robin Mecklem
Jamie Sue Willard
Alissa Wesche
John Parmer
Kevin Eisenbeis
Ellen Armentrout
David Wright

Researchers in attendance: None

Absent: Dave Douches, Marco Scarpetta

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting:

Minutes from the July 2003 meeting were discussed and approved.

Old Business: Simon Peterson-Jones has not contacted the Biosafety Officer for follow-up regarding his contingent approval of his renewal registration document IBC # 725.

The Biosafety Officer noted that the annual assurance documents for registrations greater than one year old and greater than two years old will be sent to the Principal Investigators shortly.

The online form now allows the Principal Investigator to use his/her name and access code (code provided to access the worker training database) to enter the online registration system.

New Business: Jan Byrne was introduced as the newest member of the IBC. She is a Plant Pathologist for the Plant Biology department.

Three registrations were reviewed. The discussion and voting actions were as follows:

IBC #: 742 (Gregg Howe): The committee approved the registration; however, the Principal Investigator will be requested to complete information related to the vector in use relative to *Agrobacterium* host as well as to clarify whether the transgenic plants will be in a reproductive stage at the time that they are transported from the greenhouses/growth chambers. If the plants are reproductive at that stage, further containment of the plant material for transport (i.e. closed, leakproof containers) should be implemented and reflected in the form. The ORCBS Biosafety Staff will work with the Principal Investigator to incorporate these details in the registration.

IBC IBC # 743 (Craig Webb): The committee approved the registration, but noted that the exposure incident follow-up information should reflect Van Andel policy, not MSU. The ORCBS Biosafety Staff will work with the Principal Investigator to make this modification as well as to modify the on-line form language to address this need in the future. Additionally, the Principal Investigator will be requested to provide a copy of his animal use approval and human subjects approval forms for the IBC file.

IBC # 745 (Hans Kende): The committee approved the registration; however, the Principal Investigator will be requested to include information related to the use of *Agrobacterium* under the "recombinant system" section of the form. The ORCBS Biosafety Staff will work with the Principal Investigator to incorporate these details into the registration.

The next IBC meeting was scheduled for Wednesday, September 24, 2003 from 9 to 10:30am in the ORCBS conference room.

The motion was made and seconded to adjourn.

Prepared by:
Jamie Sue Willard, Ph.D
Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

September 24, 2004
9:00 am to 10:30am
ADOL Conference Room

In attendance:

Ned Walker
John Gerlach
Susan Ewart
Bob Silva
Patrick Venta
George Anderson
Marco Scarpetta
Patty Weber
Jan Byrne
Robin Mecklem
Jamie Sue Willard
Alissa Wesche
John Parmer
Steve Bolin

Researchers in attendance: None

Absent: Dave Douches, Rebecca Grumet

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting:

Minutes from the August 2003 meeting were discussed and approved.

eye diseases
Old Business: Simon Petersen-Jones laboratory was inspected by the ORCBS Biological Safety Team and it was determined that he will not be using lentiviral vectors in his laboratory. The vectors will be created at another institution (information from this facility still pending) and shipped frozen to Dr. Petersen-Jones research group. Any laboratory manipulations will be in contained equipment (i.e. centrifuges with sealed rotors) for aerosol containment before transport to the surgical suite. The vector administration will be performed under surgical conditions in the [REDACTED] room on the main floor of the [REDACTED] [REDACTED] with a blunted needle device. No aerosol generation is anticipated. } 7

New Business: Alissa Wesche provided a report of the registration and annual assurance document activities.

IBC #746 - Zeevaart, Jan & Steven Schwartz... Approved.

The PI identified knockout mutants in the non-technical summary and will be requested to submit information to clarify whether the knockout production is part of this registration or another registration. The ORCBS Biosafety Staff will work with the PI to incorporate these details in the registration.

IBC # 758 - Zeevaart, Jan... Approved as written.

IBC # 747 - Garavito, Michael... Approved as written.

IBC # 752 - He, Sheng Yang... Approved.

The PI will be requested to provide clarification regarding the site of plant generation and containment for transport of plants between facilities if applicable. The ORCBS Biosafety Staff will work with the PI to incorporate these details in the registration.

IBC # 753 - Larkin, Robert... Approved as written.

IBC # 754 - Arvidson, Dennis... Return for more information.

The committee requests clarification of information regarding the plant use including the following questions: are whole plants being used or simply the leaves? Are the plants themselves transgenic? The PI will also be requested to reconcile information as requested by a committee member:

IBC # 755- Walton, Jonathon... Return for more information.

Although the documentation for this registration, as well as the plant containment level were deemed appropriate, the committee raised concerns regarding the possible employee exposure hazards associated with aerosolization of fungi. The ORCBS Biosafety Team will arrange to meet with the PI and work in conjunction with MSU Occupational Health to determine if additional safety practices and protective equipment are required. Leo Mendoza will also be contacted by the IBC for further information related to health risks associated with *Cochliobolus carbonum*.

IBC # 759- Ohlrogge, John... Approved as written.

IBC # 750: Michael Kron....Approved as written.

IBC # 756- Hunt, Henry... Approved.

The PI will be requested to refine information regarding the location of the

procedures to include "ADOL", as well as to correct the information regarding the animal use committee review date (currently indicates a future date). The ORCBS Biosafety Staff will work with the PI to incorporate these details in the registration.

IBC #757- Arvidson, Cindy... Return for more information.

The PI will be requested to provide more specific information regarding the gene or insert under study. The committee suspects that this project will be using a library, but this needs to be clarified on the form. It is also indicated in some portions of the form that procedures using *Neisseria meningitidis* is included as part of this registration, although that is not fully addressed in the recombinant system section of the form. If *Neisseria meningitidis* is not part of this registration, it should be dropped from the form entirely. If it is to be included as part of this registration, occupational health surveillance provisions must be addressed as prescribed by Dr. Michael Kron.

Other considerations the committee wanted addressed by the PI included more specific information regarding biosafety containment practices. The committee will request that the PI refine procedures to address the issue of aerosol generation (i.e. open flaming of loops) for portions of the procedure that require manipulation of the viable intact *Neisseria*. The IBC Chair and the Biosafety Officer plan to meet with the PI to discuss these issues further.

IBC #760- Frost, John ... Approved as written.

The Frost laboratory was inspected by the ORCBS Biosafety staff in relation to this registration and found to be acceptable.

The next IBC meeting was scheduled for Wednesday, October 22, 2003 from 9 to 10:30am in the ORCBS training room (C-30 Engineering Research Complex).

The motion was made and seconded to adjourn.

Prepared by:

Jamie Sue Willard, Ph.D

Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

October 22, 2004

9:00 am to 10:30 am

C-30 Engineering Research Complex (ORCBS Training Room)

Members in attendance:

Ned Walker
John Gerlach
Susan Ewart
Patrick Venta
George Anderson
Mike Rideoutt
Patty Weber
Jan Byrne
Robin Mecklem
Steve Bolin
Dave Douches

Members not in attendance: Bob Silva, Rebecca Grumet

Researchers in attendance: [REDACTED]

Others in attendance: Jamie Sue Willard, Alissa Wesche

Call to order: Ned Walker called the meeting to order and introduced the new community representative, Mike Rideoutt, who will be replacing Marco Scarpetta on the committee.

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting: Minutes from the September 2003 meeting were discussed and approved.

Old Business: Cindy Arvidson (IBC #757) has dropped *N. meningitidis* from her registration and taken action to address all items that were addressed in the ORCBS Biosafety inspection of her lab. She has proposed to address the issue of aerosolization from loop-flaming through the use of work practice controls rather than through elimination of the flame (as recommended by the IBC) because such measures are procedure-prohibitive (in reference to disposable loop use or use of BSC) or cost-prohibitive (in reference to flameless burner use). The ORCBS will provide samples of disposable loops for Dr. Arvidson to try and ask for feedback on their effectiveness and continue to discourage the use of open-flame techniques. The committee agreed that these actions were acceptable and approved the registration document based on this information.

The ORCBS Biosafety Team met with Jonathon Walton (IBC #755) to collect information about the spraying of the fungi on the plants and passed this information on to MSU Occupational Health for recommendation regarding respiratory protection. Dr. Ken Rosenman did recommend the use of a respirator for this application and the ORCBS will work with the Walton staff to adopt this practice. If objections are not voiced by the IBC committee, an approval letter will be issued once the respiratory protection requirements have been met.

New Business:

IBC #761 (Karen Friderici)

The committee approved the registration; however, the Principal Investigator will be asked to complete Question #7 on the form. The ORCBS Biosafety Team has contacted the [REDACTED] to receive documentation regarding institutional approval for this facility to produce transgenic mice for collaborators.

IBC # 763 (J. Hu)

The committee voted to approve this form although the non-technical summary was not written in a non-technical manner. The ORCBS Biosafety staff will work more closely with each Principal Investigator to assure that the level of information is appropriate for future reviews.

IBC # 764 (Sarah Elsea)

The committee voted for contingent approval of this registration. The Principal Investigator will be requested to modify the project summary information to better explain the progression of activities that are to be captured with this document. Additionally, the ORCBS Biosafety Team will work with Dr. Elsea to address any issues of containment of animals for transport (if applicable), and to verify that animal housing is appropriate for containment of transgenic rodents. Revisions and followup to be reviewed by the IBC Chair for final approval.

IBC # 767 (Peter Wolk)

The committee voted to approve the registration. The Biosafety Staff will follow-up on conflicting information regarding transport of materials and disinfection of liquids.

[REDACTED] BIOSAFETY/BIOSECURITY MANUAL: Select agent registration is being sought by [REDACTED]. [REDACTED] was present to provide an introduction of the lab's function and purpose and answer initial questions on the part of the committee. Controlled copies of the manual were issued to the committee and members were asked to review and redline the document within the next two weeks (November 4). Once redlines are complete, members should

contact the Biosafety Team for pick-up of the documents. The BSO will compile & incorporate the redlines for the final draft of the document to be distributed for review and approval at next month's meeting.

The next IBC meeting was scheduled for Tuesday, November 18, 2003 from 9 to 10:30am at Room 164 Giltner Hall.

The motion was made and seconded to adjourn.

Prepared by:
Jamie Sue Willard, Ph.D
Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

November 19, 2004

9:00 am to 10:30 am

C-30 Engineering Research Complex (ORCBS Training Room)

Members in attendance:

John Gerlach
Susan Ewart
George Anderson
Mike Rideout
Patty Weber
Robin Meeklen
Steve Bolin
Dave Douches
Robert Silva

Members not in attendance: Rebecca Grumel, Ned Walker, Patrick Venta

Researchers in attendance: None

Others in attendance: Kevin Eisenbeis, Ellen Armentrout, Jamie Sue Willard, Arissa Wesche

Call to order: John Gerlach

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting: Minutes from the October 2003 meeting were discussed and approved.

Old Business: The [REDACTED] Biosafety/Biosecurity Manual was approved as written. All future additions and revisions will be submitted to the committee for further review.

Discussion from the committee regarding the on-line registration: Indicated that there are still items outstanding for revision on the form. The ORCBS Biosafety Team will work with the ORCBS information systems personnel to complete the revisions. Items that will be addressed:

1. The feasibility of developing the "recombinant system" portion of the form so that it captures systems in a single manner rather than grouping up to 3 systems together will be explored.
2. Questions related to vectors will be modified to capture whether these are commercially available or research-generated.

3. Inclusion of "containment level" for genetically modified animals.
4. Dropping the first portion of the question related to aerosol-generation and simply asking for information related to how aerosols are minimized.
5. Any remaining typographical errors.

New Business:

IBC #771 (Cynthia Miranti)

The committee voted for contingent approval of this registration. The Principal Investigator will be asked to modify item #10 to reflect BSL-2 exposure incident response procedure and to list the mouse cell lines that will be used as host materials. The revisions and follow-up will be reviewed by the IBC Chairman for final approval.

IBC #769 (Nick Duesbery)

The committee voted for contingent approval of this registration. The Principal Investigator will be asked to complete all applicable questions in the recombinant system section of the document as well as to provide further information on pDES and whether this is a commercially available vector or research generated. Additionally, the details of the exposure incident follow-up procedure must be included. Regarding containment of the animals for transport, the Principal Investigator will be asked to use secondary containment of the animals for transport between the laboratory areas, as well as to describe how animals will be contained when used in the laboratory. Additionally, the committee requested that the Principal Investigator provide information on record keeping, holding (security) and final disposal of the research animals.

IBC #751 (Sulaiman Bughara)

The committee voted to return this registration for more information. The Principal Investigator will be asked to provide documentation from the collaborator regarding the applicability of the notification to the proposed release sites. Although plant release guidelines were attached addressing containment in a general manner, the ORCBS Biosafety staff will work with the Principal Investigator to address a number of specific questions raised by the committee. A permanent record of the specific questions are on file. Revisions will be resubmitted to the committee at a later date for further consideration.

The next IBC meeting was scheduled for December 30, 2003 from 9 to 10:30am at C-30 Engineering Research Complex.

The motion was made and seconded to adjourn.

Following the meeting, committee members were provided with a tour of the mobile BSL-3 facility that will be registered for select agent work.

Prepared by:

Jamie Sue Willard, Ph.D.

Biological Industrial Hygienist, OROBS

INSTITUTIONAL BIOSAFETY COMMITTEE MEETING
December 30, 2003
9:00 am to 11:30 am
C-30 Engineering Research Complex (ORCBS Training Room)

Members in attendance:

George Anderson
Steve Bolin
Dave Douches
Susan Ewart
Rebecca Grumet
Robin Mecklem
Robert Silva
Ned Walker
Patty Weber

Members not in attendance: Jan Byrne, John Gerlach, Michael Rideoutt, Patrick Venta

Researchers in attendance: Jose Cibelli

Others in attendance: Ellen Armentrout, David Wright, Alissa Wesche

Call to order: Ned Walker

Roll Call: As noted by Alissa Wesche

Discussion of minutes from last meeting: Minutes from November 2003 meeting were discussed and approved.

New Business:

IBC #777 (Donna Koslowsky)

The committee voted for contingent approval of this registration. The Principal Investigator will be asked to identify the baculovirus gene she is disrupting to better verify that environmental risk is minimized, as well as to better explain the work being done in tissue culture and to clarify the nature of the plasmids in use. The issue of BSL assignment was also discussed as the organism in use is classified as a Risk Group 2 organism.

IBC #782 (Loic DeJardin)

The committee voted for contingent approval of this registration. The Principal Investigator will be asked to address the following questions:

1. What genes have been deleted to make the adenovirus non-infectious/non-replicative (i.e., E3, E4 or both)?
2. Is there the potential for recombination with other endogenous adenoviruses (knowing the answer to question 1 will essentially answer this question)?
3. What is the potential for the spread of the adenovirus beyond the wound site into the rest of the rabbit's body?
4. Clarification under C.c.ii. (name of the host in which the insert will be expressed): wound repair cells *from rabbits*
5. Clarification of technical summary to better outline the steps of the procedure

If Dr. DeJardin cannot address questions 1 and 2 due to the confidentiality concerns of the collaborating group providing the vector, the committee would approve the registration with the information from questions 3-5 and an upgrade to Animal Biosafety Level 2.

IBC #783 (Bart Williams)

The committee voted for contingent approval of this registration. The Principal Investigator will be asked to change the answer to question 8 to "Yes" to reflect the fact that he will be working with transgenic mice. In addition, the committee also expressed concern that Dr. Williams only provided examples of the genes that could "number in the hundreds". To alleviate this concern, Dr. Williams will be asked to upgrade his lab biosafety level to BSL-2 and to add information regarding the containment conditions for transgenic animals at [REDACTED]

IBC #784 (Alex Chen)

The committee voted for contingent approval of this registration. The Principal Investigator will be asked to modify question 9 to reflect spill response procedures, as well as to attach a technical summary that better explains the progression of activities that are to be captured with this document (i.e., what is he going to be doing with the transgenic mice).

Jose Cibelli

Dr. Cibelli provided the committee with a brief introduction of his research aims and more specifically his plans covered in the animal use forms currently under review by the AUCAUC.

Based on this information, the work captured under these AUFs does not involve recombinant DNA molecules in the traditional sense of the NIH Guidelines, although many of the techniques needed to get to the research stage outlined in the AUFs do require recombinant DNA molecule use. These techniques have yet to be registered with the IBC but the ORCBS Biosafety Staff will work with the Cibelli lab staff to assure that this is accomplished in a timely manner.

The committee posed a number of questions to Dr. Cibelli that were relative to environmental release and security measures. These questions will be kept on

file for further consideration if needed. The committee did conclude that research of a sensitive nature should be reviewed by the committee with an emphasis on environmental release and security as well as sound biosafety practices in light of a "standard" for reviewing such work.

Amanda Fine, *Mycobacterium bovis*: Survival in the Environment

This project was brought before the committee for review at the request of Robin Mecklem after being contacted by John Baker regarding the nature of the research. The IBC concluded that several other entities need to be informed of the project scope and be given an opportunity for input in the project design, including the state veterinarian, the state TB interagency committee, the Dean of the College of Veterinary Medicine, and the DCPAH Director.

Upon further discussion, the committee decided that this does not really fall under the committee's purview. It was decided that the IBC did not want to "take the lead" on this and instead suggested that this go before other individuals/committees, such as the state bovine TB committee.

Meeting adjourned: 11:30 AM

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

January 28, 2004

9:00 am to 10:30 am

C-30 Engineering Research Complex (ORCBS Conference Room)

Members in attendance:

George Anderson

Mike Rideoutt

Robin Mecklem

Patrick Venta

Ned Walker

Rebecca Grumet

Members not in attendance: John Gerlach, Patty Weber, Dave Douches, Robert Silva, Steve Bolin, Susan Ewart, Jan Byrne

Researchers in attendance: None

Others in attendance: John Parmer, Jamie Sue Willard, Alissa Wesche

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting: Minutes from the December 2003 meeting were discussed and approved.

Old Business: Alissa Wesche provided an update as to the progress of pending reviews. Approval of the Koslowsky, Chen and Petersen-Jones registrations are still pending due to unfulfilled requests for additional information.

New Business:

IBC # 776: DellaPenna, D. ... approved as written.

Discussion of this document was mainly about the layout of questions on the new form, not the PI's information. Based on this discussion, revisions will be made to the "recombinant system" of the form to differentiate questions relative to the host.

IBC # 779: Wiseman, R. ... approved as written.

The ORCBS biosafety staff will be inspecting the lab February 4, 2004 for compliance with BSL-2 and bloodborne pathogens exposure control requirements.

IBC # 787: Trail, F. ... approved.

The PI will be asked to provide more extensive information regarding plant inoculation techniques and pathogenicity testing. This information will be reviewed by the IBC Chair and IBC members with plant expertise for final approval.

The next IBC meeting was scheduled for Thursday February 26th, from 3 to 4:30 p.m. Location to be announced prior to the meeting.

The motion was made and seconded to adjourn.

Prepared by:
Jamie Sue Willard, Ph.D
Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

February 26, 2004

3:00 pm to 4:30 pm

302 USDA Avian Disease and Oncology Laboratory

Members in attendance:

George Anderson
Mike Rideoutt
Robin Mecklem
Patrick Venta
Ned Walker
Rebecca Grumet
John Gerlach
Dave Douches
Jan Byrne
Steve Bolin
Robert Silva

Members not in attendance: Patty Weber, Susan Ewart

Researchers in attendance: None

Others in attendance: Jamie Sue Willard, Alissa Wesche

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting: Minutes from the January 2004 meeting were discussed and approved.

Old Business: Alissa Wesche provided an update as to the progress of pending reviews. Approval of the Koslowsky, Chen and Petersen-Jones registrations are still pending due to unfulfilled requests for additional information.

New Business:

Policy Action: After much discussion regarding the applicability and ambiguity of the "recombinant DNA molecule" definition outlined in the NIH Guidelines, the committee decided that any registration where the work outlined may meet this definition depending on one's interpretation, will be reviewed by the committee. In other words, when in doubt, a registration will be reviewed.

Policy Action: A number of registrations that have been reviewed and require further action by the Principal Investigator (PI) are still outstanding. The committee concurred that it is appropriate to give Principal Investigators 15 days from the time that they are notified of the required actions to respond if they wish to have their registration addressed further at the next IBC meeting to receive full approval. The PIs will also be notified that if some sort of response is not received within 45 days of the notification, their registration will be considered inactive. The ORCBS Biosafety staff plans to implement the use of this written notification effective immediately.

IBC # 793 Martha Mulks... Approved as written.

The PI has already met with the URCF and ORCBS Biosafety staff regarding procedures for animal husbandry, observation, sample collection and necropsy. New staff will complete entry/PPE training with URCF staff prior to the project start. The PI will be asked to modify the BSC location information to accurately reflect where lab applications may be taking place. The ORCBS Biosafety staff will perform a re-inspection of the Mulks lab if the bacteriological work will be conducted there.

IBC # 788: Justin McCormick ... approved as written (with minor corrections).

The ORCBS Biosafety Staff will advise the PI to modify the exposure response information to reflect the use of human cells, and to change the response to Question 8 to accurately reflect the scope of the document. The ORCBS Biosafety staff will also perform a formal lab inspection (an informal inspection was performed in preparation for this review by Alissa Wesche) to assure that biosafety requirements are discussed and implemented as needed.

IBC # 792: Michael Bagdasarian ... Return for more information.

The PI will be asked to provide more extensive information regarding the plasmids in use. There were a number of biosafety-related issues with the documentation that need to be addressed including: applicability of the use of a BSC, completion of a pre-project meeting with ULAR staff for the animal portion of the study, and no completion of a biosafety inspection at the current lab location. The ORCBS Biosafety Staff will attempt to schedule another lab inspection/consultation with the lab staff and will report back to the committee next month.

IBC # 789: Ken Sink ... Approved (with minor corrections).

The PI will be advised of modifications required for the spill response information which currently indicated that waste will be treated with bleach and autoclaved. The response to Question 8 needs to be modified based on technical summary of the proposed document. The PI will also be advised that the approval is limited to the scope of applications and inserts that are listed in the document.

IBC # 794: Randolph Beaudry ... Approved as written.

The PI will be advised of the need to address any permitting requirements for movement of the plants as well as the possible need for human subjects registration by the collaborator in Florida for the quality tests to be performed at that location.

The next IBC meeting was scheduled for Wednesday March 24, 2004 from 3 to 4:30 p.m. The meeting will be held at the DCPAH facility (room to be announced prior to the meeting).

The motion was made and seconded to adjourn.

Prepared by:
Jamie Sue Willard, Ph.D
Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

March 24, 2004

3:00 pm to 4:30 pm

DCPAH Library/Conference Room

Members in attendance:

George Anderson
Susan Ewart
Robin Mecklem
Patrick Venta
Ned Walker
Rebecca Grumet
Dave Douches
Steve Bolin
Robert Silva
Patty Weber

Members not in attendance: Jan Byrne, John Gerlach, Mike Rideoutt

Researchers in attendance: None

Others in attendance: Kevin Eisenbeis, Jamie Sue Willard, Alissa Wesche

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting: Minutes from the February 2004 meeting were discussed and approved. It was noted that the approval status of "approved as written...with minor corrections" was inaccurate. This status should be changed to "contingent approval".

Old Business: Alissa Wesche provided an update as to the progress of pending reviews. The outstanding registrations from Chen and Petersen-Jones have been reviewed and have received final approval. The Koslowsky and Bughrara registrations remain in the final review process.

New Business: The modified recombinant DNA on-line form was distributed to the IBC committee for review. No new comments were made regarding the form.

Policy Action: None

Registration Reviews:

790 Scott Fitzgerald....Contingent Approval

The PI has been asked to define whether or not the BCG vaccine is inactive. The RB51 is inactivated; however, no mention was made as to whether the BCG was live or inactive. Additionally, the PI states in his objectives that "several different vaccines" will be used, while only specifically mentioning the BCG and RB51 vaccines. Clarification must be made here. Also, the PI stated that the mice will be taken from the [REDACTED] to the [REDACTED] for necropsy. The committee requested further information regarding the rationale for off-site necropsy and addressing containment issues associated with transport.

#796 Miriam Sticklen....Approved as written

This registration was a straight forward document and no questions were raised from the committee.

#798 Bin Teh...Approved as written

This registration was approved as written; however, the committee requested information regarding the origin of the human cancer cell lines (i.e., whether they were ATCC or NIH cell lines). The ORCBS Biosafety staff has visited with the PI and determined that these cell lines were indeed purchased from the ATCC.

The next meeting was scheduled for Thursday, April 29th from 3:00 to 4:30pm at the C-30 Engineering Research Complex. If this will not work for your schedule, please let me know as soon as possible so that we can reschedule if needed.

The motion was made and seconded to adjourn.

Prepared by:

Jamie Sue Willard, Ph.D

Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

April 30, 2004

3:00 pm to 4:30 pm

C-30 Engineering Research Complex

Members in attendance:

George Anderson
Mike Rideoutt
Robin Mecklem
Patrick Venta
Ned Walker
Rebecca Grumet
John Gerlach
Dave Douches
Jan Byrne
Steve Bolin
Robert Silva
Susan Ewart

Members not in attendance: Patty Weber

Researchers in attendance: None

Others in attendance: Jamie Sue Willard, Alissa Wesche

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of minutes from last meeting: Minutes from the March 2004 meeting were discussed and approved.

Old Business: Wesche & Mecklem reported that the field release registration form is now available on the website as a word document. Affected departments were offered an informational presentation on the form- Crop & Soil Science received the presentation in March. All other affected department chairs were sent written information to be distributed to their research personnel. Alissa Wesche provided an update as to the progress of pending reviews.

New Business:

751 Bughrara, Suleiman....Contingent Approval

The PI will be asked to provide clarification on plot size and verification that the registration is only for the Ingham County site. Additionally, the PI will be asked to provide information regarding the general nature of the genes and promoters.

FR-001 DiFonzo, Christina ... Contingent Approval

This was the first of the field release documents to be reviewed by the committee and stimulated extensive discussion over the scope of information necessary for review and the IBC's role for risk assessment and "approval" of field release registrations. *Provisions of the NIH Guidelines do permit substitution of IBC review in circumstances where the project is already reviewed and approved by a federal agency. For field releases requiring a USDA notification or permit, this provision may apply but proposed NABC Field Release standards are founded on the assumption that an IBC is reviewing, approving, and conducting surveillance of field release-related activities. Guidance from the General Counsel's Office, Kevin Eisenbeis & David Wright will be sought.*

The committee concurred that for the DiFonzo registration, the plot location should be minimally disclosed to the Biosafety Officer for recordkeeping and incident preparedness purposes because the proposed site is off-campus. The BSO will contact the General Counsel's office regarding protection of information before pursuing this matter with the PI.

FR-002 Kell, James... Approved as written

This field release registration captured Kell's ongoing activities, the performance standards that are followed and release locations (which were all on campus property).

#799 LaPres, John...Approved as written

The Biosafety Team will work with the PI to address minor items on the registration document (completion of registration status box, clarification of HBV vaccination offer under medical surveillance requirements). The Biosafety Team will also perform an inspection of the lab for BSL-2 and BBP compliance.

#803 Lenski, Richard... Approved as written

#804 Mansfield, Linda... Approved as written

The PI will be asked to remove reference to the pig work as the approval at this stage is for the mouse model only. The Biosafety Team will also perform an inspection of the lab for BSL-2 compliance.

#805 MohanKumar, P.S. ... Return for more information

The PI will be asked to submit documentation verifying the proportion of the viral genome in this vector in order to support the assignment of animal BSL-1 facilities and procedures for maintenance of the animals. The proposed location for this work must be reviewed for BSL-2 facility features and lab staff must complete all requirements of the personnel at risk of bloodborne pathogens exposure under MSU BBP Exposure Control Plan (i.e., training, HBV vaccination offer, implemented use of safer needle devices). The Biosafety Team will work with this lab to address these issues and will report on progress at next month's meeting.

The next IBC meeting was scheduled for Thursday, June 3rd, 2004 from 3 to 4:30 p.m. The meeting will be held at C-30 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:

Jamie Sue Willard, Ph.D

Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

June 2, 2004

3:00 pm to 4:30 pm

C-30 Engineering Research Complex

Members in attendance:

George Anderson
Susan Ewart
Robin Mecklem
Patrick Venta
Ned Walker
Rebecca Grumet
Dave Douches
Steve Bolin
John Gerlach
Mike Rideoutt
Jan Byrne

Members not in attendance: Patty Weber, Robert Silva

Researchers in attendance: Scott Fitzgerald

Others in attendance: Chuck Reid, Kevin Eisenbeis, John Parmer, Ellen Armentrout, Jamie Sue Willard, Alissa Wesche, Amber Bitters

Call to order: Ned Walker

Roll Call: As noted by Jamie Sue Willard

Discussion of the agenda: The agenda was passed after amendment. Chuck Reid would be attending the meeting to discuss the role of the IBC and land management in field release situations. Also, new information on the Mohankumar registration would be added.

Discussion of minutes from last meeting: Minutes from the April 2004 meeting were discussed and approved.

Old Business: Alissa Wesche provided an update as to the progress of pending reviews. The Bagdasarian registration was 45 days outstanding; however, he has contacted the Biosafety team to set up an inspection of his laboratory.

New/Ongoing Business: Dr. P.S. Mohankumar has been contacted regarding the necessary changes to his document and laboratory requirements discussed in the April 2004 meeting. Inconsistencies existed between the IBC registration

and Animal Use Form with this specific research. The committee discussed the role of the IBC and AUCAUC when animals are involved in research governed by the NIH guidelines. Dr. David Wright will be contacted to determine if the IBC approval is required before the AUCAUC can be approved or if the IBC, at a minimum, should have the AUCAUC information before making a decision on the registrations.

Chuck Reid (MSU Land Management), Ellen Armentrout and Kevin Eisenbeis were present to discuss the role of the IBC and Land Management Office in field release of genetically-modified plants and to discuss the proposed USDA changes for permits in the future.

Round table discussion ensued on the topic and conclusions were:

- The IBC may be able to reduce its role to a recordkeeping function for field releases as these must have USDA permits if plants are genetically-modified or are classified as pests.
- There is the potential for internally-funded research involving genetically-modified plants to be undertaken without a permit; this could be curtailed if a system is developed that requires notification of Land Management, and IBC approval (via verification that permit/notification documents are in place) prior to plot assignment.
- The parties present at the meeting will work towards developing and implementing a system to assure that field releases are properly captured and that plots meeting permit restrictions are assigned.
- Gary Lemme will be asked to attend the next IBC meeting to provide an update on the NABC "Field Release Performance Standards" as this will likely affect the IBC's and field managers' roles in field releases as well.

Registration Reviews:

790 Scott Fitzgerald (amended)....Approve as written

The Principal Investigator was present to discuss the changes to his registration and any safety considerations that evolved from these changes. The vaccine is an active, live replicating *Brucella abortus* vaccine. However, the research is conducted at BSL-3 conditions at the [REDACTED], which will cover any containment or biosafety issues associated with the use of the virus. All necropsies will be conducted at the [REDACTED] in a biosafety cabinet on the BSL-3 necropsy floor or alternatively in the BSL-2 poultry necropsy lab in a BSC with respiratory protection regardless of final location.

#805 Miriam Sticklen....Approved as written

This registration was a straight forward document and no questions were raised from the committee.

#FR-003 Rebecca Grumet...Approved as written

This registration was approved as written. The trials will look at field performance of genetically-altered plants. The plots from the previous year will be assessed on a weekly basis for volunteer plants.

The next meeting will be scheduled at a later date.

The motion was made and seconded to adjourn.

Prepared by:

Jamie Sue Willard, Ph.D

Biological Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

August 25, 2004

3:00 pm to 4:30 pm

C-30 Engineering Research Complex

Members in attendance:

George Anderson
Robin Mecklem
Patrick Venta
Ned Walker
Rebecca Grumet
Steve Bolin
John Gerlach
Mike Rideoutt
Jan Byrne
Robert Silva
Patty Weber

Members not in attendance: Susan Ewart, Dave Douches

Researchers in attendance: None

Others in attendance: Kevin Eisenbeis, Ellen Armentrout, Loran Bieber, Jamie Sue Willard, Amber Bitters

Call to order: Ned Walker

Roll Call: Introductions of committee members and meeting attendants were made to Loran Bieber. The roll call was noted by Jamie Sue Willard.

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes from the June 2004 meeting were discussed and approved.

Old Business: Amber Bitters provided an update as to the progress of pending IBC reviews. Robin Mecklem and John Gerlach discussed the activities and recriminations surrounding Sulieman Bughrara's Kentucky Bluegrass field release trials. Information and documentation regarding the plots was obtained and it was determined that the responsibilities of the Institutional Biosafety Committee were met.

New/Ongoing Business: Dr. Lemme has been asked to attend an IBC meeting to discuss regulatory affairs surrounding the field release of genetically-modified

plants. He was unable to attend the June or August 2004 meetings. He will be asked to attend the September 2004 meeting to discuss NABC "Field Release Performance Standards."

The following modifications to the online registration form were suggested:

- Indicating on the form that acronyms alone are not acceptable. All acronyms should also be written out within the document.
- Making the assumption that all laboratory protocols contain steps that produce aerosols rather than asking whether aerosols will be produced. The principal investigator will only have to indicate how these will be contained.
- Adding a place to indicate whether the vector to be used is commercially available.

Registration Reviews:

#792 Michael Bagdasarian....Contingent Approval

The document was approved provided that the animal use portion of the registration be removed. This information will be captured in a separate registration document. The Principal Investigator must also ensure that the biological safety cabinet he will be using for the work has a current certification. The Biosafety Team will perform a laboratory inspection to ensure that the room being used meets BSL-2 requirements.

#810 Dean DellaPenna....Contingent Approval

The registration document was approved with the following changes. The strain(s) of *Escherichia coli* used as a vector will be identified. The nptII insert will be identified with further information. The source of the Gene Fluorescent Protein (GFP) will be identified. It will be assumed that biological aerosols will be produced during the laboratory procedures and the Principle Investigator will be asked to describe in the document how these are to be contained. Information will be provided on the management of exposure incidents. It will be made clear whether the project will require the transportation of materials and if so how these items will be transported. A procedure to be used for biological material spill response will be described in the registration document. It has been determined that liquid biohazardous waste will be generated. This change will be captured in the document along with treatment and disposal procedures for this waste.

#812 Cynthia Miranti....Contingent Approval

The Principal Investigator will be using a gene silencing system. The document was approved with changes. The changes include clarifying the eukaryotic source (cDNA and siDNA) of the genes to be inserted. The document will be modified to capture the recommendation for Hepatitis B vaccination for anyone working with the human cell lines. The document will be modified to ensure that all acronyms used are also written out. It will be determined whether the gene

silencing system is commercially available and whether the human cells lines were obtained from the Centers for Disease Control.

#813 James Galligan....Contingent Approval

The registration was approved with changes. Clarification regarding the transportation of materials is required. Will the Principal Investigator will be transporting materials or only receiving them. This information will be clarified in the registration document. The document will also be modified to ensure that all acronyms used are also spelled out within the document. A laboratory inspection will be conducted by the Biosafety Team to ensure that the lab space used by the Principal Investigator meets BSL-2 requirements.

The next meeting was scheduled for Wednesday, September 22, 2004 from 3:00 to 4:30 pm at the Diagnostic Center for Population and Animal Health, room 155.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

September 22, 2004

3:00 pm to 4:30 pm

115 Diagnostic Center for Population and Animal Health

Members in attendance:

George Anderson
Patrick Venta
Ned Walker
Rebecca Grumet
Steve Bolin
Jan Byrne
Robert Silva
Susan Ewart

Members not in attendance: Dave Douches, John Gerlach, Mike Rideoutt, Patty Weber

Researchers in attendance: None

Others in attendance: John Parmer, Kevin Eisenbeis, Ellen Armentrout, Loran Bieber, Jamie Sue Willard, Gary Lemme, David Eberline

Call to order: Ned Walker

Roll Call: The roll call was noted by Jamie Sue Willard.

Discussion of the agenda: The agenda was approved with the addition of the FR-004 (Suleiman Bughrara) documentation.

Discussion of the minutes from last meeting: Minutes from the June 2004 meeting were discussed and approved with minor changes to the Della-Penna paragraph (i.e. *Escherichia* was misspelled and host should be used instead of vector in the second sentence).

Old Business: An update of the outstanding registrations was provided by Jamie Sue Willard.

New/Ongoing Business: Dr. Gary Lemme attended the meeting to discuss the NABC's "Field Release Performance Standards" for genetically-modified plants. Dr. Lemme provided the committee with the draft of the "Recommendations for Field Trials with Transgenic Plants". The draft will go to the NABC for voting action this week. Once it is approved at the Federal level, it will go to Institutions across the United States for approval as well. The draft defines what role the IBC

and other regulatory committees will fulfill in terms of field release issues. Continued discussions were held regarding the MSU IBC's role in field release documents. Currently, the IBC does not vote on field release documents if an APHIS permit has been issued. However, committee members, as well as other personnel on campus, have voiced their concern with this approach. Research will be conducted by the ORCBS Biosafety staff to determine what options the University can take for oversight of this type of research. A report will be prepared for the committee and affiliates for consideration in the future.

The following modifications to the online registration form were suggested:

- In the non-technical summary, 8th grader should be bolded so researchers write the summary in non-technical terms.

Registration Reviews:

#816 Dean DellaPenna....Approved as written (with clarifications)

Clarification was requested in the Insert section under part a. The committee questioned whether this should be marked "no" and the information removed. The E.coli is more likely to be a shuttle vector and not a true insert. The promoter, CaMV, should be typed out in full. Additionally, question 5 in the Specific Containment Practices section states they are not re-using sharp devices; however, in question 7, they have marked the needles will be re-capped. Clarification was requested to see if they were recapping for re-use or disposal. If for re-use then question 5 must be changed to "yes".

FR-004..Sulieman Bughrara...no action

No voting action occurred on the field release document as the Principal Investigator supplied the approved APHIS permit. Additional information provided by the Principal Investigator, including site location and boundary regulations, was handed out at the meeting for informational purposes. At this time, the IBC does not vote on field releases if a permit has been granted.

The next meeting was scheduled for Thursday, October 21, 2004 from 2:00 to 3:30 P.M. at C-30 Engineering Research Complex (ORCBS Training Room).

The motion was made and seconded to adjourn.

Prepared by:

Jamie Sue Willard, Ph.D

Interim Biosafety Officer, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

October 21, 2004

2:00 pm to 2:30 pm

C-30 Engineering Research Complex (ORCBS Training Room)

Members in attendance:

George Anderson

Patrick Venta

Jan Byrne

Robert Silva

Susan Ewart

Dave Douches

John Gerlach

Mike Rideoutt

Members not in attendance: Patty Weber, Steve Bolin, Rebecca Grumet, Ned Walker

Researchers in attendance: None

Others in attendance: John Parmer, Loran Bieber, Jamie Sue Willard, David Eberline

Call to order: John Gerlach

Roll Call: The roll call was noted by Jamie Sue Willard.

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old Business: Information regarding outstanding registrations was provided by Jamie Sue Willard.

New/Ongoing Business: No new business was discussed.

Registration Reviews:

#818 Suzanne Thiem....Approved (with minor editing)

The committee voted to approve the registration with minor editing. The amendments included the removal of the terms "various", "other model

membrane proteins" and "other membrane receptors" from the Insert sections b.ii and b.iii.

#820 Katherine Osteryoung...Approved (with minor editing)

This registration was originally submitted as 3-F (exempt) to a committee member for review based on her previous submittal three years prior as an exempt registration. However, upon closer review the document was determined to be 3-E. The committee voted to approve the registration with the classification changed to 3-E. Additionally, it was noted in the "Further Risk Identification" section that the question stating...altering an animal genome with recombinant DNA or testing viable-recombinant DNA modified microorganisms in whole animals...should be marked yes. However, the NIH would have to be contacted for clarification on this matter.

The next meeting was scheduled for Monday, November 22, 2004 from 3:00 to 4:30 P.M. at the Avian Disease and Oncology Laboratory (ADOL) conference room.

The motion was made and seconded to adjourn.

Prepared by:

Jamie Sue Willard, Ph.D, RBP
Interim Biosafety Officer, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

November 22, 2004

3:00 pm to 3:30 pm

Avian Disease and Oncology Laboratory Conference Room

Members in attendance:

George Anderson
Patrick Venta
Robert Silva
Dave Douches
John Gerlach
Ned Walker

Members not in attendance: Patty Weber, Steve Bolin, Rebecca Grumet, Michael Rideoutt, Jan Byrne, Susan Ewart

Researchers in attendance: None

Others in attendance: John Parmer, Loran Bieber, Jamie Sue Willard, Amber Bitters

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters.

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old Business:

Information regarding outstanding registrations was provided by Jamie Sue Willard. It was decided that Ned Walker would work with Dean DellaPenna to facilitate the revisions to his outstanding registrations.

A summary of the exempt documents reviewed in the past month was given by Amber Bitters.

New/Ongoing Business:

The following suggestions were made regarding the registration form:

- The committee would like the old registration form removed from the website
- The committee would like the online form to be adapted to capture permit requirements

Ned Walker notified the committee of the resignation of Susan Ewart. Possible replacements were discussed. Loran Bieber will contact Dr. John Kruger regarding serving on the committee. Dr. John Fyfe was decided on as an alternate in the case that Dr. Kruger declines.

There was a discussion regarding the lack of activity in the past months. It was suggested that researchers working with plants and/or plant materials may not be aware of the need to register their work. Dave Douches and Rebecca Grumet will be provided with a list of those plant researchers who have registered with the IBC, so they can develop a list of those who may need to be contacted regarding the registration process.

Registration Reviews:

IBC #821... Gloria Perez... Contingent Approval

The committee would like verification that appropriate import permits are/were obtained for the research animals.

The next meeting was scheduled for Tuesday, January 18, 2005 from 3:00 to 4:30 P.M. at the Avian Disease and Oncology Laboratory (ADOL^o) conference room.

The motion was made and seconded to adjourn.

Prepared by:

Amber Bitters

Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

February 22, 2005

3:00 pm to 3:45 pm

C-124 Engineering Research Complex

Members in attendance:

George Anderson

Patrick Venta

Robert Silva

John Gerlach

Ned Walker

Patty Weber

Steve Bolin

Michael Rideoutt

John Kruger

Jamie Willard

Members not in attendance: Rebecca Grumet, Dave Douches, Jan Byrne

Researchers in attendance: None

Others in attendance: Kevin Eisenbeis, Loran Bieber, Amber Bitters

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters.

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old Business:

The status of IBC registration #821 (Perez, Gloria) was questioned. There was initially a question regarding the need for a permit for the importation of animals for the project. The PI stated that she would be ordering the mice from Jackson Laboratories rather than importing them from Canada as was originally planned.

New/Ongoing Business:

A discussion was initiated by Pat Venta regarding the proper classification of experiments involving human genes being inserted into *E. coli* via a bacterial

plasmid and then expressed in a human cell line. The discussion stemmed from a PI inquiring about the proper categorization of her experiment. It was decided that further discussion would take place at the March 22nd meeting.

Registration Reviews:

IBC #824, Jose Cibelli, Approved (with minor editing)

The PI had assigned the registration to review category 3-F. The committee feels it falls under category 3-E and approved the registration with this change.

IBC #826, Karen Friderici, Approved (with minor editing)

The registration involves the use of whole animals (mice) and therefore requires the identification of the animal facility where they will be housed. The committee approved the registration provided this additional information is given.

IBC #910, Hongbao, Ma, Contingent Approval

It was decided that approval of this registration would be contingent upon the following items. The laboratory where work will be conducted [REDACTED] must pass a BSL-2 laboratory inspection. The committee also decided that the mice used in the project should be housed at the [REDACTED]. As the mice will contain microorganisms that are both zoonotic and recombinant, it was felt that this would be the most appropriate facility to use. The committee would like further clarification in the project summary regarding the mouse portion of the project. This information was accessed through the Animal Use Form submitted by the PI, however this information should also be included in the rDNA registration. The PI had marked in the Insert section (C. b. iv.) under Recombinant System that greater than 2/3 of the eukaryotic source genome would be inserted. The committee believes that this was a misunderstanding of the question and that it should be marked less than 1/2.

The next meeting was scheduled for Tuesday, March 22, 2005 from 3:00 to 4:30 P.M. Location to be announced.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

March 22, 2005

3:00 pm to 3:30 pm

C-124 Engineering Research Complex

Members in attendance:

George Anderson
Robert Silva
John Gerlach
Ned Walker
Patty Weber
Steve Bolin
John Kruger
Rebecca Grumet

Members not in attendance: Dave Douches, Jan Byrne, Jamie Willard, Pat Venta, Michael Rideoutt

Researchers in attendance: None

Others in attendance: Kevin Eisenbeis, John Parmer, Amber Bitters

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters.

Discussion of the agenda: The revised agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old Business:

An update was given regarding the status of IBC registration #907 (Ma, Hongbao). The lab space where the project will be carried out was inspected, however nothing was set up at that time. The PI was advised of proper waste disposal, limiting access to the lab, proper signage, training requirements, etc. Another inspection will be conducted after the lab is set up for work. The PI was also advised to contact the [REDACTED] to obtain space for the animal work and to complete an Animal Hazard Control Form.

Discussion of the NIH Guidelines in regards to expression of mammalian genes in tissue culture of the same mammal with an exempt bacterial plasmid was postponed until the April meeting. Pat Venta had initiated the discussion and as

he was absent from the meeting it was decided that further discussion should wait until he was present.

Registration Reviews:

IBC #828, Dodgson, Jerry, Contingent Approval

The PI used the old registration form and the committee would like to know the additional information that is captured in the newer online version of the form. Specifically, the committee would like to know how biological materials are being transported from the lab to the poultry facility. This is to ensure that it is done in a manner that prevents environmental release. Also, the committee would like to know how the animals are going to be disposed of.

IBC #829, Triezenberg, Steve, Contingent Approval

The PI used the old registration form and the committee would like to know the additional information that is captured in the newer online version of the form. Additional information that needs to be captured includes:

- The date of last certification of the biosafety cabinet that the PI will be using
- Exposure incident management
- Additional medical precautions- As the project proposes the use of human cells lines all lab personnel who will be handling the human-derived materials are required to be in the Bloodborne Pathogen Program and be offered the hepatitis B vaccine
- Use of sharps devices including what devices will be used, if they will be reused, and if they will be recapped
- Transportation of biological materials in a manner to prevent release
- Use of surface disinfectants
- Disposal of liquid biohazardous waste
- The location of the autoclave that will be used for decontamination of solid biohazardous waste

The next meeting was scheduled for Tuesday, April 26, 2005 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

April 26, 2005

3:00 pm to 4:30 pm

C-124 Engineering Research Complex

Members in attendance:

George Anderson

Robert Silva

John Gerlach

Ned Walker

John Kruger

Dave Douches

Jan Byrne

Jamie Willard

Pat Venta

Members not in attendance: Steve Bolin, Rebecca Grumet, Patty Weber, Michael Rideoutt

Researchers in attendance: Jerry Dodgson

Others in attendance: John Parmer, Amber Bitters, Stephanie Smith-Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters.

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

New Business:

Patty Weber asked that a discussion of the registration document in regards to expanding the questioning on transportation be included on the agenda for this meeting. Patty Weber could not make it to the meeting, therefore the discussion was postponed and will be included on the agenda for the next meeting.

Old Business:

An update was given regarding the status of IBC registration #907 (Ma, Hongbao). There has been no change since the last meeting. Work has not yet

begun. The PI has not yet set up a meeting with the [REDACTED] and ORCBS to complete an Animal Hazard Control Form.

Discussion of the NIH Guidelines in regards to expression of mammalian genes in tissue culture of the same mammal with an exempt bacterial plasmid was postponed until the next meeting.

Registration Reviews:

IBC #923, Dodgson, Jerry, Contingent Approval

This project involves work with a collaborator at another facility. The committee would like documentation that the work done there has received approval by the Institutional Biosafety Committee for the facility. The committee would also like the registration to contain information regarding disposal of the animals.

IBC #913, Kelly, James, Approved

This registration was approved with the addition of the location of the greenhouse space that will be used for the project.

IBC #916, Tiedje, James, Contingent Approval

Before granting full approval, the review committee would like additional information on the gene inserts to be used. The committee would also like additional information on what materials the PI intends to transport and for what purpose they will be transported.

IBC #921, Schwartz, Richard, Contingent Approval

This registration was approved on a contingent basis. The committee would like the registration to outline which genes were removed from the Moloney murine leukemia virus. The committee would also like additional information on the packaging/helper system that the PI is using in this project.

IBC #830, Linz, John, Returned for More Information

The committee would like additional information before making a decision on this registration. The PI is using aflatoxin producing *Aspergillus*. The committee would like clarification on whether genes involved in the production of aflatoxins are being cloned. The committee would also like to know if aflatoxins are being produced, and if so in what quantity.

IBC #831, Dong, Ke, Approved

This document was approved as written.

Field Release Registration Reviews:

FR-005, DiFonzo, Christina, Incomplete

This document was found to be incomplete. The registration asks for the appropriate permit to be attached. This document contained an approval notification from the Environmental Protection Agency but did not contain a permit for release from the United States Department of Agriculture- Animal and Plant Health Inspection Service.

FR-006, DiFonzo, Christina, Complete

This field release registration document was found to be complete.

FR-007, Sink, Ken, Complete

This field release registration document was found to be complete.

The next meeting was scheduled for Tuesday, June 7, 2005 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

June 7, 2005

3:00 pm to 4:30 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson
Robert Silva
John Gerlach
Ned Walker
Dave Douches
Jamie Willard
Steve Bolin
Rebecca Grumet
Patty Weber
John Kruger

Members not in attendance: Jan Byrne, Pat Venta

Others in attendance: Kevin Eisenbeis, Stephanie Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Stephanie Edwards

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

New business:

Michael Rideoutt, a community committee member, has resigned from the committee. Dr. George Anderson will contact an acquaintance from the Michigan Department of Community Health, and ask her to serve on the committee. Other options for finding a community member include Sparrow Health System and Hospice.

The committee discussed ordering letterhead specific for the Institutional Biosafety Committee, rather than continuing the use of letterhead designed for the Office of Radiation, Chemical and Biological Safety. The ORCBS will work on samples to bring in for the next meeting.

Old business:

An update was given regarding the status of IBC registration # 907 (Ma, Hongbao). The PI still needs to set up a meeting with the [REDACTED] and ORCBS to complete an Animal Hazard Control Form.

Patty Weber discussed expanding the questioning on transportation on the registration document. A question should be included in the document on the location where the materials will be transported (building or room).

The discussion of the NIH Guidelines in regards to expression of mammalian genes in tissue culture of the same mammal with an exempt bacterial plasmid was postponed until the next meeting.

Registration Reviews:

IBC #924, Schwartz, Richard, Approved

The committee would like the laboratory biosafety level changed from BSL-1 to BSL-2 and the animal biosafety level changed from ABSL-1 to ABSL-2. The registration document should also be modified to include containment information (i.e. decontamination, personal protective equipment, etc.).

IBC #1672, Sticklen, Mariam, Approved

This registration document was approved with changes. The committee would like to know the strain of Agrobacterium that the PI will be using as a vector and as a host for gene expression. The committee would also like clarification on where the plants will be transported, why the PI is using a vehicle to transport them, and how the plants will be contained in the vehicles. The registration listed the PI as the only person who will be working on this project. The committee would like verification of this. Additional minor changes include the biosafety cabinet certification date and the location of the autoclaves she will be using.

IBC #1674 Pestka, James, Contingent Approval

This registration was approved on a contingent basis. The committee would like the PI to provide information on two of the listed vectors: pPICE A and pPICE B. The committee would like to ensure that they have standard known features that comply with the guidelines. The committee would also like clarification on the biological activity of the inserts. Additional changes to the registration document that the committee would like made include: writing out the inserts rather than using abbreviations, indicated the fraction of the genome that the insert represents, and stating in the document that the cell lines being used for expression are human cell lines.

IBC #1676, Triezenberg, Steve, Approved

The committee would like the PI to change the secondary container used for transport from a cardboard box to a container that will contain all leaks or spills of material if the primary container ruptures.

IBC #1677 Weliky, David, Approved

This document was approved as written.

IBC #1680 Sordillo, Lorraine, Approved

This registration document was approved with the following minor changes. The committee would like the PI to change the approximate fraction of the insert to less than $\frac{1}{2}$, and to clarify biological spill response procedures.

FR-008, Grumet, Rebecca, Complete

This field release registration document was found to be complete.

The next meeting was scheduled for Thursday, July 21, 2005 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

July 21, 2005

3:00 pm to 4:00 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson

John Gerlach

Ned Walker

Jamie Willard

Steve Bolin

Jan Byrne

Members not in attendance: Pat Venta, Dave Douches, Rebecca Grumet, John Kruger, Robert Silva, Patty Weber

Others in attendance: Kevin Eisenbeis, Amber Bitters

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

New business:

It was discussed and decided on that an email account will be set up specifically for IBC use.

A discussion ensued regarding field release procedures. It was determined that Chuck Reid should have been informed of all field release documents that are reviewed by the committee. This was not done in the past but he will be sent copies of all field release documents that have been reviewed this year and he will be informed of all future field release documents that are reviewed by the committee.

Old business:

Dr. John Gerlach contacted an acquaintance from the Michigan Department of Community Health, and spoke to her about serving on the committee. Dr. Jamie Sue Willard will contact this person and invite her to observe the next meeting.

Letterhead options were reviewed and a design was decided on. The ORCBS will order letterhead to be used for official IBC communications.

The discussion of the NIH Guidelines in regards to expression of mammalian genes in tissue culture of the same mammal with an exempt bacterial plasmid was postponed until the next meeting.

Registration Reviews:

IBC #753, Yan, Hanggao, Approved with changes

Both the technical and the non-technical summaries were very short. The committee would like the registration document to include additional information in the summaries to ensure that the scope of the project is sufficiently defined. It should also include information on the plasmid that is being used.

FR-009a-d, Kells, James, Incomplete

The committee would like additional information regarding these releases. The committee would like to know why there is not a current memo from the Michigan Department of Agriculture (MDA). The memo provided was dated March 5, 2002. The registration did include a current (March 15, 2005) memo from the United States Department of Agriculture authorizing movement and release of the materials. The committee would like to ensure that the MDA has been notified of this intent to release and that regulatory changes in this area have not occurred within the last three years.

The next meeting was scheduled for Tuesday, August 30, 2005 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

August 31, 2005

3:00 pm to 4:10 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson

John Gerlach

Ned Walker

Jamie Willard

Steve Bolin

Rebecca Grumet

Pat Venta

Robert Silva

Betty Schoepke

Members not in attendance: Dave Douches, John Kruger, Patty Weber, Jan Byrne

Others in attendance: John Parmer, Theresa Kelley, Amber Bitters

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: A discussion of the field release procedures was added to the agenda. The agenda was approved with the addition.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old business:

The committee had a brief discussion of the NIH Guidelines in regards to expression of mammalian genes in tissue culture of the same mammal with an exempt bacterial plasmid. It was decided that these registrations will be categorized as 3-E and reviewed by the entire committee. If the registrations to be reviewed at each meeting become too numerous this topic will be revisited.

The current field release procedures, as written by Ned Walker, were reviewed and discussed by the committee. It was decided that the document was accurate as written and would be distributed, as appropriate, for further evaluation.

Registration Reviews:

IBC #1685, Coussens, Paul, Approved with changes

The committee had a few minor questions regarding this registration. The commercially available eukaryotic virus-based vector was described as being HTLV I. The committee questioned whether this was a mistake as the company information describes the vector as an HIV based one. The committee would like clarification of this point. The PI also named several specific genes that will be used as inserts, however the PI also indicated that various, as yet, undetermined, additional genes will be used in the future. The committee would like this statement removed from the registration and would like the PI to notify the committee via the ORCBS of the specific additional genes to be used when that time comes.

IBC #1692, Mansfield, Linda, Approved with Changes

The committee would like a clarification to be made regarding the genes that will be used. The PI specifically named some genes and stated that "others are unnamed." The PI also needs to indicate that all personnel handling human materials will be in the Bloodborne Pathogen Program and will be offered the Hepatitis B vaccination.

IBC #1695, Grumet, Rebecca, Approved

This registration was approved as written.

IBC #1697, Cibelli, Jose, Contingent Approval

The approval of this registration is contingent upon the final disposition of the animals used. Other minor things to be addressed include: answering the question related to spill response and the question related to permit-required shipments.

IBC #1698, He, Sheng-Yang, Approved with changes

The committee would like the biological activity of the inserts to be used clarified in the registration document. Comments received by committee members after the meeting include:

- clarify which strain/pathovar of *P. syringae* that is being used
- clarify what plants will be used... tobacco, tomato, etc.

FR-009a-d, Kells, James, Complete

The PI provided documentation stating that the materials used for field release are no longer regulated.

The next meeting was scheduled for Tuesday, September 20, 2005 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

September 20, 2005

3:00 pm to 3:45 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson

John Gerlach

Ned Walker

Jamie Willard

Steve Bolin

Pat Venta

Robert Silva

John Kruger

Jan Byrne

Members not in attendance: Dave Douches, Betty Schoepke, Patty Weber, Rebecca Grumet

Others in attendance: John Parmer, Kevin Eisenbeis, Amber Bitters

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old business:

Ned Walker reported on the status of field release review procedures. Further procedure review will be postponed until the position of Michigan Agricultural Experiment Station Director has been filled.

New business:

It was discussed and decided on that the IBC should be expanded by one member with expertise in plant research. Kevin Eisenbeis will present to the committee a list of possible candidates.

Registration Reviews:

IBC #1700, Last, Robert, Approved with change

This registration outlines the use of a host-vector system that contains a kanamycin-resistance marker. Although the host (*Arabidopsis thaliana*) does not naturally acquire this drug resistance trait, the vector is a standard, commercially available system. The PI, therefore does not need to answer yes to the question regarding the deliberate transfer of drug resistance traits.

IBC #1702, Jiang, Ning, Approved with changes

This registration outlines the use of a Pack-MULE-CBF gene in an *Oryza sativa*-pCAMBIA1300 host-vector system. In the Non-Technical Project Summary the PI mentions using "other candidate genes." These genes are not described anywhere else in the registration. The genes to be used needs to be clarified by the PI.

IBC #1711, Amalfitano, Andrea, Denied

This registration outlines three separate projects. The committee would like these projects put into separate registrations. Two of the projects (Projects #1 and #2) are similar enough to be included in one registration, however the third project must be captured in a separate registration. The separation of the third project is necessary not only to facilitate the review process but to assign appropriate containment levels, personnel protective equipment, animal facilities, etc. to all of the work.

The committee had many questions regarding the registration. The main clarifications that the committee would like include:

- Additional information on the alpha virus based VEE replicon
- Clarification on the host cells to be used- primary or cell lines
- Information on what the fowlpox will be used for
- The animal facilities to be used for each project
- The biosafety levels at which each project will be conducted
- Clarification on what work is being conducted at Duke and what work will be conducted here
- Additional information for Project #2 (much of the information regarding the recombinant system seems to be missing from the registration)
- Several minor items including biosafety cabinet certification, transportation of materials, use of sharps, spill response, etc.

The registration used to capture Projects #1 and #2 will be distributed to the committee members and final comments will be gathered electronically, if the registration is ready for final review before the next meeting. As the registration was reviewed in a formal meeting once, this method was determined to be appropriate. The registration used to capture Project #3 will be reviewed during

a regular meeting, as there were sufficient questions to warrant another full review.

The next meeting was scheduled for Tuesday, November 1, 2005 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

November 1, 2005

3:00 pm to 3:45 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson
Robert Silva
John Gerlach
Ned Walker
Dave Douches
Jamie Willard
Steve Bolin
Rebecca Grumet
Pat Venta
Jan Byrne

Members not in attendance: John Kruger, Betty Schoepke, Patty Weber

Others in attendance: Kevin Eisenbeis, John Parmer, Amber Bitters, Stephanie Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Stephanie Edwards

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old business:

An update was given regarding status of IBC registration # 907 (Ma, Hongbao). The PI did not get the grant, and can be taken off the registration list.

New business:

The committee discussed getting a new IBC community member. Betty Schoepke resigned from the position.

Registration Reviews:

IBC #1710, Patterson, Ronald, Pending

This registration was returned for more information. The committee would like more information for the non-technical and technical project summaries. Pending approval until information is complete.

IBC# 1714, Worden, Robert, Approved with Clarification

The committee had questions regarding the classification of the project:

- Why the project was classified as a 3-D rather than 3-E?
- Will the individual experiments involve greater than 10 liters?
- Why is the Biosafety level at 2?
- Under section C. Insert b. iv. The committee wanted to know if the PI was using $\geq 2/3$ of the section of the cDNA or the entire genome?

IBC# 1720, Teh, Bin Tean, Approved with Clarification

The committee would like to know if knockout mice are being made in [REDACTED]

The committee would also like clarification on whether the insert will be expressed in whole animals.

IBC# 1716, Amalfitano, Andrea, Pending with Clarification

The committee is pending approval until the delegates meet with the PI to clarify what work will be done at MSU and what work will be done at Duke.

The next meeting was scheduled for Wednesday November 30, 2005 from 3:30 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:

Stephanie Edwards

Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

January 24, 2006

3:00 pm to 4:30 pm

C-124 Engineering Research Complex

Members in Attendance:

Jean Fierke

John Gerlach

Ned Walker

Jamie Willard

Dave Douches

Robert Silva

Patty Weber

Rebecca Grumet

Jan Byrne

Members not in attendance: Steve Bolin, John Kruger, Patrick Venta, George Anderson, and Judith Williams

Others in attendance: Kevin Eisenbeis, John Parmer, Amber Bitters, and Stephanie Smith-Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved as written.

Old business:

We had a new community member present, Jean Fierke. Judith Williams has also been brought on as a community member.

New business:

Jamie Willard gave an update on select agent use on campus. The university currently has one select agent laboratory. The lab has asked to add an additional organism, Avian Influenza, to the registration. Also discussed and decided was that the IBC will still review select agent protocols, and manuals. The Biosafety Manual, Biosecurity Manual and Emergency Response Manual are currently being revised and will be reviewed by the committee before being implemented by the University.

Kevin Eisenbeis discussed field release information. Possible upcoming changes include increased security, auditing, and financial proof of responsibility in the event of a release.

Dr. Ned Walker will contact the Agriculture Experiment Station for help in the dissemination of a reminder to plant-related departments to submit field release registrations.

Registration Reviews:

IBC #1732, Smith, George, Approved with clarifications

This registration focuses on the identification of local regulatory molecules that control growth of ovarian follicles and quality of the eggs that these follicles contain. The PI needs to identify what genes he plans on manipulating. He also needs to list the grants that are covered by this registration.

IBC #1726 Xiao, Hua, Approved with clarifications

This registration outlines the role of the transcriptional cofactor TIP30, and its associated factors, in the regulation of cell growth and tumorigenesis. The PI needs to clarify if he will be producing the TIP30 knockout mice here at MSU, or if they have already been developed and will be shipped here. Clarification is also needed on the virus used. Is the virus wildtype, or has it been modified? The PI needs to clarify if the virus is infectious to mice and if it is the animal research must be performed at an ABSL-2.

IBC #1727, Zheng, Yong-Hui, Returned for more information

This registration focuses on innate intracellular immunity to HIV/AIDS. The committee had many questions regarding the registration. The main clarifications that the committee would like to be included are:

- A more in depth explanation on what the PI is doing in the research
 - Classification should be changed from a IIIE to a IIID
 - Because human use is checked off in project information, the committee would like to know if there will be blood drawn from human subjects;
 - a) if so sharps should be discussed
 - Clarify APOBEC protein genetic manipulations
 - Discuss the techniques used for the three goals
 - Change the disinfection section to a bleach wipe down and follow up with an ethanol or a quat.
-

The next meeting was scheduled for Tuesday, February 28, 2006 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:

Stephanie Smith-Edwards

Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

February 28th, 2006

3:00 pm to 4:00 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson

Pat Venta

John Gerlach

Ned Walker

Jamie Willard

Steve Bolin

Rebecca Grumet

Jan Byrne

Jean Fierke

Members not in attendance: John Kruger, Dave Douches, Patty Weber, Robert Silva

Others in attendance: Kevin Eisenbeis, Stephanie Smith-Edwards, John Parmer

Call to order: Ned Walker

Roll Call: The roll call was noted by Stephanie Edwards

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

New business: Judith Williams resigned, currently looking for a new community member.

Old business: Discussed computer glitches with the registration form.

Registration Reviews:

IBC #1727, Zheng, Yong-Hui, Approved with minor clarifications

The committee would like corrections made in the Recombinant DNA Use: Further Risk Identification section. "No" is marked on the using human or animal pathogen DNA cloned into non-pathogenic prokaryote or lower eukaryote. Also "No" is marked for using infectious animal or plant DNA or RNA viruses in tissue culture... Both questions should be marked "Yes". The Specific Biocontainment Practices section, Exposure Control # 3, discusses sharps devices used in research. The committee would only like marked the sharps that will be used in the lab. Uncheck "blood collection systems", and "needle/ syringe", if it is not actually used in the lab.

IBC# 1737, Olson, Karl, Approved with contingency of fish removal

The committee would like the fish removed from the lab because it is a violation of CDC, NIH, and AAALAC regulations.

The CDC and NIH guidelines state: Animals not involved in the work being performed are not permitted in the lab.

The next meeting was scheduled for Tuesday, March, 28, 2006 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:

Stephanie-Smith Edwards

Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

March 28, 2006

3:00 pm to 3:30 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson

Jan Byrne

Jean Fierke

John Gerlach

Rebecca Grumet

Robert Silva

Pat Venta

Ned Walker

Patty Weber

Members not in attendance: Steve Bolin, Dave Douches, John Kruger, Jamie Willard

Others in attendance: John Parmer, Kevin Eisenbeis, Amber Bitters, Stephanie Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old business:

An update on registration documents pending and/or receiving approval was given by Amber Bitters:

- **IBC #1710, Patterson, Ronald**

The registration was originally reviewed at the November 1, 2005 meeting and was returned for more information. The PI has verbalized that he is still intending on doing the project and will provide the requested information within 30 days. If the additional information is not provided within that timeframe, the registration will be inactivated.

- **IBC #1714, Worden, R. Mark**
The registration was originally reviewed at the November 1, 2005 meeting and was approved with minor clarifications. The PI has verbalized that he is still intending on doing the project and will make the requested clarifications to the registration within 30 days. If the clarifications are not made within that timeframe the registration will be inactivated.
- **IBC #1727, Zheng, Yong-Hui**
The registration was originally reviewed at the February 28, 2006 meeting and was approved with minor clarifications. The PI has since made those clarifications and the registration received full approval on March 3, 2006.
- **IBC #1737, Olson, Karl**
The registration was originally reviewed at the February 28, 2006 meeting and received approval contingent on the removal of non-research related fish from the laboratory. The PI has since removed the fish from the laboratory and full approval of the registration was granted on March 3, 2006.

Registration Reviews:

IBC #1734, Burton, Jeanne, Approved

This registration outlines the transformation of coliform bacteria to express green fluorescence protein. The transformed bacteria will be used to evaluate neutrophil-pathogen interactions in vitro. The project will be carried out under BSL-2 containment conditions. The registration was approved with no modifications.

IBC #1739, Shiu, Shunhan, Approved

The goal of this project is to uncover small, novel coding sequences between 90-300 base pairs within the *Arabidopsis thaliana* genome. The genes of interest will be cloned into a binary vector containing expression tags and transformed back into *Arabidopsis* to determine if they are being made into proteins. The committee felt that the registration was generally acceptable and posed no major concerns. The PI indicated that the vector to be used was not commercially available; the committee felt that this was a mistake and requested that the PI be asked to clarify this. The work will be carried out at PBSL-1.

IBC #1740, Cibelli, Jose, Approved

The goal of this work is to create a parthenogenetically derived non-human primate cell line that can substitute for the use of embryonic stem cells in future studies. The PI will use a commercially available lentiviral vector system to create a cell line which constitutively expresses H19 siRNA and then test the differentiation potential of the cell line. The lab portions of the work will be

completed under BSL-2 containment conditions, while the animal work will be conducted at ABSL-1.

The next meeting was scheduled for Tuesday, April 25, 2006 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

April 25, 2006

3:00 pm to 3:40 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson

Steve Bolin

Jean Fierke

John Gerlach

Rebecca Grumet

Pat Venta

Ned Walker

Jamie Willard

Members not in attendance: Jan Byrne, Dave Douches, John Kruger, Robert Silva, Patty Weber

Others in attendance: John Parmer, Kevin Eisenbeis, Amber Bitters, Stephanie Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: A discussion of IBC policies was added to the agenda. The agenda was approved with the additional item.

Discussion of the minutes from last meeting: Minutes were approved as written.

New business:

There was a discussion of what standard operating procedures are in place for the IBC. Specifically addressed was the amount of time that should be given to PIs to revise their registration documents after they have been reviewed by the committee. It was thought that a document may have been developed to address this in the past. The ORCBS Biosafety Team, with the assistance of Ned Walker will pull together the procedures that were put together in the past. These procedures will be reviewed and discussed at the next meeting.

Old business:

An update on registration documents pending and/or receiving approval was given by Amber Bitters:

- **IBC #1710, Patterson, Ronald**
The registration was originally reviewed at the November 1, 2005 meeting and was returned for more information. The PI has verbalized that he is still intending on doing the project and will provide the requested information within 30 days. If the additional information is not provided within that timeframe, the registration will be inactivated.
- **IBC #1714, Worden, R. Mark**
The registration was originally reviewed at the November 1, 2005 meeting and was approved with minor clarifications. The PI has verbalized that he is still intending on doing the project and will make the requested clarifications to the registration within 30 days. If the clarifications are not made within that timeframe the registration will be inactivated.

Dr. Ned Walker reported that he had sent out a notification to plant-related departments regarding registration of field release projects. It was determined that the notification may not have reached the PI level, so a reminder will be sent out.

Registration Reviews:

IBC #1691, Haywood, J.R., Approved with clarifications

This registration outlines the study of the involvement of nitric oxide and superoxide in the control of neurotransmitters in the paraventricular nucleus of the brain during high blood pressure. Replication incompetent adenoviral vectors will be used. The committee would like a clarification on the source of the vectors as the PI indicated in the registration that the vectors are not commercially available. Other minor clarifications that need to be made to the registration include:

- Indicating the approximate fraction of the eukaryotic source genome (i.e., human cDNA) that is being used as an insert,
- Writing out the promoter that will be used rather than using an abbreviation,
- Clarifying which of the project materials are being transported and whether those materials are potentially infectious at the time of transport,
- Indicating what procedures will be used in the event of a spill of biological materials, and
- Clarifying whether liquid biohazardous waste will be generated.

IBC #1741, Jump, Donald, Approved with clarifications

This registration is a renewal of IBC registration #712. It outlines a multi-faceted approach to evaluate the role specific proteins play in the control of lipid metabolism and the onset and progression of chronic diseases. Transgenic, recombinant adenoviral and transfection approaches will be used. Several minor clarifications need to be made to the registration document, including:

- Indicating the approximate fraction of the eukaryotic source genome that is being used as an insert,
- Changing the animal biosafety level to ABSL-2 rather than ABSL-1, and
- Modifying the spill procedures to include at least a 10 minute contact time when using bleach solution as a disinfectant.

IBC #1742, Kroos, Lee, Approved with clarifications

This registration is a renewal of IBC registration #713. The research involves the study of gene expression during sporulation of *Bacillus subtilis* and *Myxococcus xanthus*. Work will be conducted at BSL-2. The PI indicated in the registration that scalpels that are used to harvest *M. xanthus* from agar plates would be reused. The committee would like the registration to include a more detailed description of how these devices will be safely processed after use.

FR-011, Douches, David, Complete

This field release registration was found to be complete as written. A copy of the registration will be sent to Chuck Reid, Land Management.

The next meeting was scheduled for Thursday, June 1, 2006 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:

Amber Bitters

Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

June 1, 2006

3:00 pm to 3:40 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson
Steve Bolin
Dave Douches
Jean Fierke
John Gerlach
Rebecca Grumet
John Kruger
Pat Venta
Robert Silva
Ned Walker
Jamie Willard
Patty Weber

Members not in attendance: Jan Byrne

Others in attendance: John Parmer, Amber Bitters, Stephanie Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved with the addition of action on the 04/25/2006 meeting minutes.

Discussion of the minutes from last meeting: Minutes were approved as written.

Old business:

An update on registration documents pending and/or receiving approval was given by Amber Bitters:

- **IBC #1710, Patterson, Ronald**
The registration was originally reviewed at the November 1, 2005 meeting and was returned for more information. The PI did not provide the requested information and the registration was inactivated.
- **IBC #1714, Worden, R. Mark**
The registration was originally reviewed at the November 1, 2005 meeting and was approved with minor clarifications. The PI did not provide the requested information and the registration was inactivated.

The committee reviewed and discussed the draft standard operating procedures (SOPs) that were developed. Further discussion will take place at the next meeting in regards to any outstanding questions; including how the committee will define notification as required by the NIH Guidelines for registrations falling under category III-E. The ORCBS Biosafety Team will make the revisions and distribute the SOPs for final review.

Registration Reviews:

IBC #2641, Allison, Richard, Approved with clarifications

This registration outlines the development of drybean, soybean and cowpea varieties that have a resistance to *Scleoritinia sclerotiarum*. The resistance gene, oxalic acid oxidase, will come from the wheat genome. The laboratory work will be conducted at BSL-1 and greenhouse work will be conducted at PBSL-1. The plants developed through this work will be used in field trials outlined in FR-012. The committee would like the principal investigator to include in the registration, the methods that will be used for transporting the seedlings from the greenhouse to the field for planting.

IBC #2643, Vande Woude, George, Returned for additional information

This registration is a renewal of IBC registration #681. The committee felt that the registration did not give an adequate amount of information to take any voting action on it. Specific information that the committee needs includes:

- Clarifying the recombinant system to be used, including the exact genes that will be inserted and their activities;
- Describing the techniques that will be used;
- Clarifying whether transgenic animals will be produced and if so, what will then be done with them or if cell lines are being used

FR-012, Allison, Richard, Complete

This field release registration was found to be complete as written. A copy of the registration will be sent to Chuck Reid, Land Management.

The next meeting was scheduled for Thursday, July 6, 2006 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

July 6, 2006

3:00 pm to 4:10 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson
Steve Bolin
Jean Fierke
John Gerlach
Rebecca Grumet
John Kruger
Pat Venta
Robert Silva
Ned Walker
Jamie Willard

Members not in attendance: Jan Byrne, Dave Douches, Patty Weber

Others in attendance: Kevin Eisenbeis, John Parmer, Amber Bitters, Stephanie Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved with the addition of discussion of the draft standard operating procedures.

Discussion of the minutes from last meeting: Minutes were approved as written.

Updates:

- An update on registration documents pending and/or receiving approval was given by Amber Bitters:

IBC #2641, Allison, Richard

The registration was originally reviewed at the June 1, 2006 meeting and was approved with clarifications. The PI provided the requested information pertaining to transportation and the registration was approved on June 19, 2006.

- An update on the select agent program was given by Jamie Willard. The Centers for Disease Control and Prevention and the United States Department of Agriculture will be here to inspect the registered select agent facility and the facility in the process of being added to the registration.

Old business:

- The committee discussed how to define notification as required by the NIH Guidelines for registrations falling under category III-E. Dr. Patrick Venta provided an excerpt from the NIH Guidelines pertaining to notification for category III-E: "For experiments in this category, a registration document... shall be dated and signed by the investigator and filed with the local Institutional Biosafety Committee at the time the experiment is initiated." Since registrations are submitted online and there is currently no provisions for using an electronic signature, the committee decided to create an additional item is the registration document that allows the principal investigator to check a box agreeing to a statement which explains that submission of a completed registration under the secure access code of the principal investigator is equivalent to a signature on the registration form and will therefore satisfy the notification requirement.
- The ORCBS Biosafety Team will make all necessary changes to the draft standard operating procedures including the provision allowing the principal investigator to make official notification of registration as required by the NIH Guidelines, through the method described above. The standard operating procedures will be sent to Kevin Eisenbeis, Director, Environmental Health and Safety, who will then distribute them to the appropriate University administrators.

Registration Reviews:

IBC #1743, Sundin, George, Approved with minor change

This registration is a renewal of IBC registration #710. The project outlined in this registration is to study the pPT23A plasmid family of *Pseudomonas syringae*. The goal of the project is to understand the extent of plasmid transfer among *Pseudomonas syringae* pathovars and to categorize the diversity of genes encoded on this plasmid family. The PI indicated in the registration that the work will be done at PBSL-1, however since the work will be done in a lab and not in a greenhouse the committee would like the registration to reflect that BSL-1 containment will be used.

IBC #2643, Vande Woude, George, Approved with minor addition

This registration is a renewal of IBC registration #681 that was first reviewed during the June 1, 2006 meeting. At that time the committee felt that the registration did not give an adequate amount of information to take any voting action on it. The PI added the requested information to the registration document and it was reviewed again. The committee felt that the information was adequate enough to take a voting action. The registration was approved with the addition of the location where employees will report in the event of an occupational exposure.

IBC #2825, Cheng, Hans, Approved with minor change

This registration is a renewal of IBC registration #717. The registration outlines a project aimed at understanding the genetic resistance to the chicken pathogen, Marek's disease virus (MDV). The committee would like the registration to reflect that when the MDV is in the chickens it is a vector pathogenic to the chickens and in some instances other related avian species. The registration should also reflect that expression will occur in both *E. coli* and in chickens. Finally, the committee would like the section regarding transportation filled out as the PI will have to transport animals from one building to another which will require the animals being transported outside.

IBC #2826, Sundin, George, Returned for additional information

This registration is a renewal of IBC registration #711. The registration outlines procedures intended to identify and understand the function of important virulence genes in *Erwinia amylovora*, which causes fire blight disease in apple trees. The committee felt that the registration did not clearly identify whether the PI would be expressing the recombinant construct. If the PI intends to do so the organism in which expression will take place needs to be clearly identified. The committee would also like the PI to clearly explain the nature of the challenge experiment including, where it will take place (i.e., the lab or greenhouse) and in what plant parts. Finally, the registration should reflect a biosafety level for both the lab work and the greenhouse work.

The next meeting was scheduled for Thursday, August 24, 2006 from 3:00 to 4:30 P.M. at C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:
Amber Bitters
Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

August 24th, 2006

3:00 pm to 4:00 pm

C-124 Engineering Research Complex

Members in Attendance:

George Anderson
Pat Venta
John Gerlach
Ned Walker
Jamie Willard
Steve Bolin
Rebecca Grumet
Jean Fierke
Patty Weber
John Kruger
Robert Silva

Members not in attendance: Dave Douches, Jan Byrne

Others in attendance: Kevin Eisenbeis, John Parmer, Amber Bitters, Stephanie Edwards

Call to order: Ned Walker

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Updates:

- * An update on registration documents pending and/or receiving approval from the July 6, 2006 meeting was given by Amber Bitters:

IBC #1743, Sundin, George

The registration was reviewed and was approved with minor changes. The PI made the required change from PBSL-1 to a BSL-1, and the registration was approved August 14, 2006.

IBC #2643, VandeWoude, George

The registration was originally reviewed at the June 1, 2006 meeting and was returned for more information. The PI added the requested information, and the

registration was approved with a minor addition at the July 6th meeting. The PI included the location where employees would report in the event of an occupational exposure, and the registration was approved July 7, 2006.

IBC #2825, Cheng, Hans

This registration was approved with minor changes. The PI added the requested information pertaining to transportation of the chickens, and the registration also reflects that expression will occur in both *E. coli* and in chickens. The registration was approved on August 11, 2006.

Old business:

- * The ORCBS Biosafety Team will make all necessary changes to the draft standard operating procedures.

Registration Review:

IBC #2826, Sundin, George, Approved with minor clarifications:

The registration is a renewal of registration #711 that was initially reviewed during the July 6, 2006 meeting. At that time the committee felt that the registration did not clearly identify whether the PI would be expressing the recombinant construct. If the PI intended to do so, the organism in which expression will take place needed to be clearly identified. The committee also wanted the PI to clearly explain the nature of the challenge experiment including, where it would take place and in what plant parts. Lastly the committee wanted the biosafety level to reflect both the lab and greenhouse work. As of the August 24, 2006 the committee approved the registration with minor clarifications, the PI needs to state that there will be an attempt to express the recombinant construct. The committee would like the names of the promoter or other regulators, and the name of the host in which the insert will be expressed. Lastly because scissors will be used in the research, the sharps section of the registration should reflect that.

IBC #2827, Ciche, Todd, Contingent Approval for a Category III F registration:

The registration outlines a project aimed at sequencing the genome of the entomophogenic nematode *Heterorhabditis bacteriophora* strain TTO1 as a representative of 45 other species that are used as biological control agents for insect pests worldwide. The committee would like the registration to state in the project summary that the PI is providing high quality DNA to [REDACTED], who will be conducting the sequencing. The PI should also state that no recombinant DNA work will be done at MSU. The committee would also like the PI to change his experiment category from III E to III F, and state that there will be no altering of an animal genome by recombinant DNA or any testing of viable recombinant DNA-modified microorganisms in whole animals.

IBC #2828, Silva, Robert, Approved as written:

The registration outlines a project whose primary emphasis is on molecular approaches to better understand which viral genes are important for immunopathogenesis and shedding

of MDV. The committee approved the registration as written. * Noted: Dr. Robert Silva did not vote on this action.

IBC #2829, Fadly, Aly, Approved as written:

The registration outlines a project with three main objectives. The first is to determine viral-, host-, and environment-related factors that influence the epidemiology, transmission and oncogenicity of avian retroviruses in poultry. The second objective is to develop and evaluate practical and economical methods for detection of avian retroviruses in field flocks. The third objective is to develop new programs for control of retrovirus infection in poultry including use of newly developed recombinant vaccines. The registration was approved by the committee as written. * Note Dr. Robert Silva did not vote on this action.

IBC #2834, Lee, Lucy, Returned for more information:

This registration outlines a project aimed at better understanding viral gene function and development of recombinant vaccine for better control of Marek's Disease. The committee felt that more information is needed in the project summary clarifying where the MEQ knockout will be sent. Also the summary needs to clarify if the MEQ knockout will be mutated and if that mutation will be reinserted. Also, in the Vectors section of the registration, the committee would like the PI to clarify what vectors she will be using. The PI should also clarify if the gene or inserts for the eukaryotic virus is really being deleted. *Note Dr. Robert Silva did not vote on this action.

IBC #2832 Fata-Hartley, Cori, Returned for more information:

The registration outlines a project aimed at understanding the replication cycle of Mengovirus. The committee felt that the project summary needed to be more specific from a molecular standpoint; explaining what types on insertions, deletions, and substitutions would be made.

The next meeting was scheduled for Tuesday September 26, 2006 from 3:00 to 4:30 P.M. location to be determined; C-124 Engineering Research Complex is occupied for this date and time.

The motion was made and seconded to adjourn.

Prepared by:

Stephanie-Smith Edwards

Biological Safety Industrial Hygienist, ORCBS

INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEE MEETING

September 26th, 2006

3:00 pm to 4:00 pm

2245 Biomedical Physical Sciences Building

Members in Attendance:

George Anderson
Pat Venta
John Gerlach
Jamie Willard
Steve Bolin
Rebecca Grumet
Jean Fierke
Patty Weber
Robert Silva

Members not in attendance: Dave Douches, Jan Byrne, Ned Walker, John Kruger

Others in attendance: John Parmer, Amber Bitters, Stephanie Edwards, Taylor Reid
(a graduate student sitting in for observational purposes)

Call to order: John Gerlach

Roll Call: The roll call was noted by Amber Bitters

Discussion of the agenda: The agenda was approved as written.

Discussion of the minutes from last meeting: Minutes were approved as written.

Updates:

- * An update on registration documents pending and/or receiving approval from the August 24, 2006 meeting was given by Amber Bitters:

IBC #2826, Sundin, George

The registration was reviewed and was approved with minor changes. The PI made the required changes, and the registration was approved September 14, 2006.

IBC #2827, Ciche, Todd

The registration originally received contingent approval. The PI changed the review category to 3-F and clarified that all recombinant work would be done at the collaborating entity. The registration received approval on September 14, 2006.

IBC #2832, Fata-Hartley, Cori

The registration was originally returned for additional information. The PI included the requested information and the registration was included on the agenda for this month.

IBC #2834, Lee, Lucy

The registration was originally returned for additional information. The PI included the requested information and the registration was included on the agenda for this month.

New business:

- * The committee reviewed a document outlining containment and security procedures for handling exempt strains of select agents. Minor changes were suggested and will be incorporated into the document by the ORCBS Biosafety Team.

Old business:

- * The draft IBC standard operating procedures were again reviewed by the committee. No changes were made and the procedures were adopted as finalized.
- * Meeting minutes requested by the Sunshine Project will be provided via the General Counsel's Office.

Registration Review:

IBC #2832 Fata-Hartley, Cori, Approved with minor change:

This registration was originally reviewed at the August 24, 2006 meeting. At that meeting the committee returned the registration for additional information. They felt that the project summary needed to be more specific from a molecular standpoint; explaining what types of insertions, deletions, and substitutions would be made. The principal investigator has provided the requested information. The registration was marked to reflect that the PI would not be using human or animal pathogens as host-vector systems. However, the committee feels that the mengovirus will be used in that capacity and that the registration should be changed to reflect that. The registration was approved with that change.

IBC #2834, Lee, Lucy, Approved as written:

This registration was originally reviewed at the August 24, 2006 meeting. At that time the registration was returned for additional information. The principal investigator provided the requested information, and the registration was approved as written.

*Note: Dr. Robert Silva did not vote on this action.

IBC #2830, Day, Brad, Returned for additional information:

This registration outlines the study of protein expression and the effects of over-expressing genes known to be involved in disease resistance in plants. The committee requested the following additional information be included in the registration:

- Clarification on exactly which genes will be used and the function of those genes;
- Method of disposal of the recombinant plant material;
- More detailed description of the transport system used when transferring materials to and from the greenhouse, laboratory and growth chambers.

In addition, the registration should be changed to reflect that drug-resistant traits are not being transferred to organisms that do not acquire them naturally.

IBC #2837, Benning, Christoph, Approved with minor change:

This registration outlines work that will be done in an attempt to understand the biosynthesis of membrane and storage lipids in plants, alga and photosynthetic bacteria. The principal investigator mistakenly marked an animal biosafety level for the work although the project does not involve the use of animals. This should be removed from the registration.

IBC #2841, York, Ian, Approved with minor clarifications:

The laboratory work outlined in this project will be conducted at biosafety level 2, however the principal investigator needs to select an animal biosafety level for the animal work. The principal investigator also needs to change the transportation section of the form to reflect that project-related animals and/or cultures will be transported. That section should also include a description of the transportation system to be used.

IBC #2842, Amalfitano, Andrea, Approved with minor clarifications:

This registration outlines an extension of work that was approved in IBC registration number 1711. The principal investigator failed to mark an animal biosafety level to be used for the animal work. This needs to be done before the registration can receive final approval. The principal investigator also needs to clarify if the project involves the shipment of materials off campus.

The next meeting was scheduled for Monday, October 30, 2006 from 3:00 to 4:30 P.M. in room C-124 Engineering Research Complex.

The motion was made and seconded to adjourn.

Prepared by:

Amber Bitters

Biological Safety Industrial Hygienist, ORCBS