

UNIVERSITY OF MINNESOTA

Twin Cities Campus

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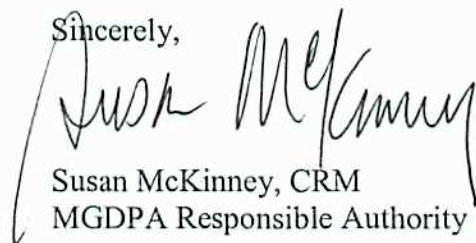
May 10, 2005

Edward Hammond
Director, Sunshine Project
P.O. Box 41987
Austin, TX 78704

Dear Mr. Hammond:

I have enclosed copies of the minutes requested. Room locations and numbers have been redacted as security information as per M.S. 13.37(a).

Sincerely,

A handwritten signature in black ink, appearing to read "Susan McKinney", is written over a horizontal line.

Susan McKinney, CRM
MGDPA Responsible Authority

Meeting Minutes
April 21, 2003
INSTITUTIONAL BIOSAFETY COMMITTEE
N101 BOYNTON HEALTH SERVICE
1:00 p.m. – 3:00 p.m.

Members Present: Chairperson Louise Hawley, Ann Fitzpatrick, John Hunt, David Somers, Mary Anne Sullivan, Cynthia Gillett, James Lauer

I. Approval of January meeting minutes
Minutes approved

II. Huang, Andrew
Study # 331
“Suppressing the Expression of Myocilin and Keratoepithelin in Ocular Tissues by Small Interfering RNA Technologies”

PI needs to clarify safety procedures.

III. Shurson, Jerry

Study # 310
“Evaluation of Potential Health Benefits of Corn DDGS Produced from Minnesota Ethanol Plants and a Polyclonal Antibody on the Ability of Pigs to Resist an Infection from Salmonella typhimurium.”

This proposal was approved with the following stipulations:

- If all strains used simultaneously, all must be susceptible to at least two classes of non-sulfa antibiotics.
- Must state which disinfectant is being used.
- Must caution those using H2 blockers.

IV. Krathwahl, Mitchell

Study # 325
“ Vaccines for Bioterrorism Using Chemokine Adjuvants”

This PI needs to respond to the following questions, which can then be reviewed administratively:

- Must state who will monitor animals on a regular basis
- Must state where vaccinia stock is coming from

- Must state whether PI is vaccinated and who else in the laboratory has been vaccinated

V. Christiansen, Stephen

Study #209

“Novel Immunotoxin Therapy for Strabismus Treatment”

This proposal was approved at meeting for ricin quantities below threshold for Federal regulations under select agent rules.

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The IBC requests, if at all possible, that the PI use hand protective material while injecting the RTA/DTA vector.

The IBC would like the PI to do an in vivo (mouse is acceptable) LD50 study of the conjugate toxin as well as the conjugate attached to antibody.

- VI. NIH/FDA decisions on retrovirus gene therapy proposals**
VII. IRB/IBC Communication

These items were not discussed due to lack of time, and will be addressed at the IBC annual program review.

Meeting Minutes

Institutional Biosafety Committee (IBC) ANNUAL PROGRAM REVIEW

June 16, 2003

2-120 MCB (Molecular and Cellular Biology)
420 Washington Ave SE
Minneapolis, MN 55455
9:00 a.m. – 4:00 p.m.

Morning Session

IBC members present: Chairperson Louise Hawley, John Hunt, Carl Jessen, Ann Fitzpatrick, Cynthia Gillett, Peter Southern, Mary Anne Sullivan, David Brown, James Lauer, Chester Whitley

IBC staff present: Melissa Nellis, Bhuma Krishnamachari

Guests present: David Hamilton (Interim VP for Research), George Chresand (Fairview Legal Counsel and Chief Compliance Officer), Adrienne Baranauskas (Fairview Research Administration), Jeffrey Perkey (IRB representative).

I. Speaker, Dr. Scott McIvor 9:00 am – 10:00 am

Dr. McIvor spoke about the current status in NIH regulations on human gene therapy. He noted that current recommendations state that all patient consent forms for retroviral gene therapy research should explicitly state that cancer has previously occurred as a result of retroviral insertion into the human genome. It is also suggested that molecular analysis occur for all subjects to be monitored for lymphoproliferative disorders, and that long-term follow-up should be offered to these subjects for up to 15 years post-treatment.

II. Milla, Carlos 10:00 am – 11:00 am

Study # 369

"A Multicenter, double-blind, placebo controlled, Phase II study of aerosolized tgAAVCF for the Treatment of Cystic Fibrosis (25E01)."

This proposal was approved with the following stipulations:

-PI must identify the specific room number and building in which the procedures will take place.

- The University of Minnesota Biosafety Officer will check the room in which the procedure will occur for negative pressure prior to initiation of this proposal, and the room must be monitored for negative pressure on each day the procedure occurs.

- PI must provide a rationale for why patients will only be held for 2 hours after the procedure. The IBC is concerned about possible exposure of the vector to other individuals. In consideration of this, the PI must provide information on the length of time vector will remain active in the patient's mucous. If vector persists past release from the hospital, then PI must address the following:

- IBC would like the patients to be held at the hospital for 24 hours post procedure, rather than 2 hours. Patients should then have restricted contact with other individuals for 48 hours after release from the hospital. Please include this in the consent form.

- Serotitres of the vector should be monitored in all people with whom the patient will have intimate contact, such as family members.

- Pregnant women, including mothers of patients must wear N95 masks when visiting with patient within 24 hours after the procedure.

- All individuals, including respiratory therapists who will come into contact with patient, must be notified of the risk of exposure to vector through mucous secretions.

- For patients who will have routine procedures to clear mucous from their chest cavity and airways, PI must identify how the mucosal sample is collected, and what the disposal method is. PI clarify any necessary precautions in the consent form.

III. Hall, Walter

11:00 am – noon

Study # 338

"A Phase III Multicenter Study of Intratumoral/Interstitial Therapy With TransMID Compared to Best Standard of Care in Patients"

Proposal was approved with the following stipulations:

- PI must provide an LD50 for this test agent.

- All individuals handling this test agent should be up to date on Diphtheria vaccinations

- PI must describe precautions (how medical instruments and or equipment will be decontaminated) post procedure to prevent the risk of prion transmission.

- Are needles used for dilution and delivery of the test agent? If so, PI must clarify if and how needles will be recapped.

- PI must clarify spill procedure in the event that the test agent is spilled. How will this test agent be neutralized?

12:00 pm-1:00 pm

Formal welcome to new IBC member David Brown

Afternoon Session

1:00 pm – 4:00 pm

I. Program Review

1:00 pm – 2:30 pm

- **Protocol Review Summary**

Bhuma Krishnamachari presented IBC statistics from 6/13/02 – 6/13/03. A summary sheet of these statistics was distributed at the program review.

- **Discussion about election of a new IBC Chair**

It was decided that James Lauer will speak to Michael Sadowsky, currently vice-chairperson of the IBC about serving as IBC chairperson, at least for the time being.

- **Response from NIH verifying University of Minnesota IBC membership to be in compliance with NIH guidelines**

We reviewed a letter sent from NIH indicating that the IBC has acted in accordance with NIH guidelines with respect to reporting membership to NIH. A copy of this letter is included along with the summary sheet of IBC statistics distributed at the meeting.

- **IBC recommendation for use of transgenic animals for Raptor Center diet**

After a discussion about the scientific and public relations ramifications of using transgenic animals for Raptor Center food, it was decided Ann Fitzpatrick or Cynthia Gillett will speak to Patrick Redig of the Raptor Center to discuss his views on this subject.

- **IBC/IRB Interaction**

Ann Fitzpatrick and Cynthia Gillett will work with Moira Keene to see if the IRB form can be adjusted to better screen for IBC related research. It was also decided that the IBC must pursue identifying human subject research that was approved prior to IBC/IRB communication efforts if they are still actively being conducted.

- **Biosafety inspection report by Darlene Charboneau**

A report was given of the current knowledge of University laboratory materials used as determined by laboratory inspections.

- **Miscellaneous procedural issues**

- Discussed possible additions to the IBC including physicians, nurses or pharmacists.

- Determined that when a proposal is reviewed at the IBC, the Principal Investigator should routinely be invited.

- For Fairview proposals reviewed by this IBC, two Fairview representatives from Infection Control at the location where research is being conducted must be present at the meeting.

II. IBC SEMINAR

3:00 pm – 4:00 pm

The first in a series of seminars presenting current issues in recombinant DNA and artificial gene transfer was "Tractable engineering of mammalian artificial chromosomes for therapeutic applications." This was presented by Ed Perkins, Ph.D., Assistant Professor of Biochemistry and Molecular Biology from the UMD School of Medicine.

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July 21, 2003
INSTITUTIONAL BIOSAFETY COMMITTEE
BOYNTON HEALTH SERVICE
1:00 p.m. – 3:00 p.m.

Members Present: Acting Chairperson Michael Sadowsky, Chester Whitley, David Somers, Mary Anne Sullivan, Cynthia Gillet, David Brown, Ann Fitzpatrick, James Lauer

Staff Present: Melissa Nellis, Bhuma Krishnamachari

I. Approval of April and June meeting minutes

Both minutes approved

II. Welcome to Michael Sadowsky as acting IBC chairperson

III. Craig Packer

Study# 304

"Infra-red Thermography as a Diagnostic Tool for Anthrax"

This proposal was not reviewed at our meeting, as PI withdrew proposal prior to meeting due to lack of funding

IV. Stephen Christiansen

Study # 277

"Novel Immunotoxin Therapy for Strabismus Treatment (initially finding the maximum tolerated dose of DR-iTox in Mice) (see April 2003 meeting minutes). Request for Change on IBC Stipulations - Dr. Christiansen and Dr. McLoon are wondering if they might be able to do a maximum tolerated dose study instead of a lethal-dose 50 study with our ricin mAb 35. They would like to use fewer animals if possible.

At meeting, IBC decided that PI must submit request to IACUC for approval. If IACUC approves this change, the IBC will be happy to review the changes as well.

V. IACUC consult

David Cornfield

0306A48921

"Developmental Regulation of O₂ Sensing in the Lung"

IBC reviewed this proposal, and discussed the implications of using sheep that may potentially carry Q-fever. Any discussion that needs to take place with

PI regarding safety concerns will occur between PI and regulatory affairs and/or DEHS.

VI. Update on communication with Raptor Center

Ann Fitzpatrick spoke with Patrick Redig of the Raptor Center, and gave us an update on the use of transgenic mice as a food source for the raptors in their facility. The Raptor center will continue this process for the time-being.

VII. Update on Paul Orchard retroviral human gene therapy trial- letter from FDA

The IBC reviewed FDA's letter to Paul Orchard indicating that he may continue his gene therapy clinical trial.

VIII. Update on July 18, 2003 CDC select agent inspection

Melissa Nellis and James Lauer gave an update on the recent CD inspection of the University.

MEETING MINUTES
October 27, 2003
INSTITUTIONAL BIOSAFETY COMMITTEE
BOYNTON HEALTH SERVICE
1:00 p.m. – 3:00 p.m.

- I. Welcome to Peter Southern as IBC chairperson**
- II. Welcome to new IBC member Michael Verneris**
- III. Welcome to new IBC staff member Claire Kari**

Members Present: Chairperson Peter Southern, , David Brown, Ann Fitzpatrick, Cynthia Gillett, John Hunt, James Lauer, Michael Sadowsky, David Somers, Michael Verneris

Members Unable to attend: Chester Whitley, Mary Anne Sullivan,

Staff Present: Melissa Nellis (IBC), Claire Kari (IBC), Jeff Perkey (IRB)

- IV. Approval of July meeting minutes**
A motion was made to approve the July min. motion was seconded and carried.

- V. Stanley Thayer**
Study# 415
" Modulation of Calcium Signaling in Neurons; HIV-1 Neurotoxicity- Mechanism and Modulation by Cannabinoids; Basic Research Center on Molecular and Cell Biology of Drug Abuse (component 5)"

The Committee decided Dr. Thayer needs to be asked in what forms (powder or liquid) are the tetrodotoxin and conotoxin supplied by the manufacturer?

If supplied in pwd form then an inhalation hazard exists and the committee needs specific safety protocols for the handling and dilution of the powder.

The committee would like to see detailed SOP's for the file and for use in the lab.

They would like included in the SOP the precautions that 2 people work together when handling the powder and one person knows the signs of poisoning, observes the other for symptoms, and knows how to get aid in the event of poisoning and vials are opened and in a biosafety cabinet.

A motion was made, seconded and carried to contact Dr. Thayer on the above points.

VI. Yoji Shimizu

Study # 432

"Structure/function analysis of T Cell beta 1 integrin

The Shimizu protocol was put on the table as an example of a proposal using recombinant Adenovirus made by using an AdEASy kit and working at safety rating. No animals are to be used all the work is done in cell culture. A motion was made to approve the Shimizu proposal, motion was seconded and carried.

Mark Jenkins

Study # 443

Costimulatory signals in CD4 + T cell activation

Mark Jenkins's proposal was also discussed as an example of a proposal using recombinant Adenovirus.

Proposed is to use an AdEASy kit to make reagents for use in cell culture and the mouse.

His proposal generated several questions about how Adenovirus exposed animals are housed.

A motion was made to approve the proposal after minor stipulations were met. Dr. Jenkins shall provide list of the specific genes involved in the proposal or the assurance that they are not genes for virulence, toxicity or antibiotic resistance. He shall notify the IBC in the form of an amendment to his proposal if new genes are added. He shall provide a safety procedure that describes how small spills are to be decontaminated.

Motion was seconded and carried.

VII. Jim Lauer introduced the topic of BSBE , Select Agents and the need for a policy to require secure facilities be provided before select agent work is done. Building and Planning committees must include planning for secure facilities.

work should have controlled access as stipulated by the CDC, the new buildings on campus and the ones being planned do not. The CDC will not approve Select Agent work in unlocked labs, from the perspective of the CDC

Vaccinia is subject to USDA inspection and inspection.

will not pass a USDA

Locked storage is not enough, labs must be secureable. Administration must be approached with a time line for remedying the problem, it must be a group effort, can't single out individual labs, the goal is to modify existing practice, the committee will draft a white paper, explain current conditions, explain what must be done, IBC will offer to help researchers work with the administration to find solutions and provide options for satisfying requirements where possible. The letter will be sent to David Hamilton and cc to Frank Cerra

Dr. Jameson's Infectious Agent proposal # 451 was discussed in the context of the unsecured space in _____ and approval cannot be granted until the issue of secure space is resolved. A motion was made and carried to contact Dr. Jameson and to withhold approval until security issues resolved.

VIII.

Laboratory and Animal Biosafety levels for gene transfer vectors: the IBC must determine policies regarding several questions. The NIH guidelines and Scott McIvor's e-mail are provided as reference. However, these decisions are ultimately the jurisdiction of the IBC, and there must be a clear stance taken on how this University will regulate research

Scott McIvor was invited to the meeting.

Scott McIvor was unable to attend. The discussion proceeded without him. The safety level of Adenovirus work and how animals used in _____ exp. are housed was discussed.

Also discussed: NIH guidelines and how should they be interpreted, have shedding studies been done, the answer was not to anyone's knowledge. Committee members suggested responsibility should be on the researcher to provide sound evidence that animals may be housed at _____

It was proposed that decisions on whether animals are kept at _____ be made case by case and wherever reasonable switch animals from _____ as soon as they are no longer shedding. A set of rules or criteria should be developed for specific viruses.

1) Should biosafety levels be assigned case by case?

- recombinant adenovirus (less than 2/3 of genome)
- retrovirus (including lentivirus, less than 2/3 of genome)
- adeno-associated virus
- transposons
- As an example NIH assigns safety levels case by case
- Should researchers be asked to assign animal housing safety levels and defend their decision if it is less stringent

No motions were made at this meeting on this topic.

What animal biosafety level will be used for animals injected with the above vectors? Specifically:

- recombinant adenovirus (less than 2/3 of genome) animal work
- retrovirus (including lentivirus, less than 2/3 of genome) animal work
- adeno-associated virus animal work
- transposons animal work
- Adeasy kits use more than 2/3rds of the Adenovirus genome but are incapable of replication
- Should the IBC ask for testing of competency

* Issues to consider:

- The guidelines appear to state (by IBC staff and by Dr. McIvor's interpretation) that certain vectors we routinely consider may actually be treated as
- Some universities have used our present approach of broadly using for most viral vectors. Others have attempted to decipher the NIH guidelines to tailor levels to each vector type (*see attachment in this packet*). The model included with this meeting packet may be used as a model.

Project #	P.I.	Project Type	Date	Approved	Summary
394	Hall	BioTox	25-JUL-03	25-JUL-03	A Multicenter Phase II St...
395	Schendel	rDNA	25-JUL-03	25-JUL-03	Lactic Acid Production Fr...
396	Schendel	rDNA	25-JUL-03	25-JUL-03	Lactic Acid Production Fr...
397	Lawther	rDNA	25-JUL-03	25-JUL-03	Expression of Bacillus th...
398	Lawther	rDNA	25-JUL-03	25-JUL-03	Expression of alzA (alraz...
399	Lawther	rDNA	25-JUL-03	25-JUL-03	Expression of HIV-1 Prote...
400	Lawther	rDNA	25-JUL-03	25-JUL-03	Expression of Epstein-Bar...
401	Lawther	rDNA	25-JUL-03	25-JUL-03	Expression of ribonucleot...
402	Lawther	rDNA	25-JUL-03	25-JUL-03	Expression of Agrobacteri...
403	Lawther	rDNA	25-JUL-03	25-JUL-03	Expression of fatty acid ...
404	Conklin	rDNA	17-SEP-03	17-SEP-03	Novel eIF Interacting Pro...
405	Cotner	rDNA	25-JUL-03	25-JUL-03	Ecological Stoichiometry ...
406	Vandenbosch	rDNA	25-JUL-03	25-JUL-03	Developmental Biology of ...
407	Koepp	rDNA	25-JUL-03	25-JUL-03	Ubiquitin ligases and Cvc...
408	Emery	InfAgent	25-JUL-03	25-JUL-03	Investigation of the Iron...
409	Seybold	rDNA	14-AUG-03	14-AUG-03	Neurotrophin-Mediated Ind...

VIII. Projects reviewed and approved by the Biosafety officer since the last meeting

<u>411</u>	Milla	InfAgent	14-AUG-03	14-AUG-03	<u>Airway Reactivity in Cyst...</u>
<u>412</u>	Lohr	rDNA	14-AUG-03	14-AUG-03	<u>The Contribution of Neura...</u>
<u>413</u>	LaParla	rDNA	14-AUG-03	14-AUG-03	<u>Microbial Observatories: ...</u>
<u>414</u>	Xing	rDNA	12-SEP-03	12-SEP-03	<u>Developing Member-Specifi...</u>
<u>416</u>	Cavert	InfAgent	12-SEP-03	12-SEP-03	<u>CNS Distribution and Geno...</u>
<u>417</u>	King	rDNA	15-SEP-03	15-SEP-03	<u>Analysis and Intervention...</u>
<u>418</u>	Orr	rDNA	15-SEP-03	15-SEP-03	<u>Cell Signaling and Neurod...</u>
<u>419</u>	McIvor	rDNA	16-SEP-03	16-SEP-03	<u>Treatment of hyperoxia in...</u>
<u>421</u>	Vallera	BioTox	23-SEP-03	23-SEP-03	<u>Development of Diphtheria ...</u>
<u>422</u>	Vallera	rDNA	23-SEP-03	23-SEP-03	<u>Development of Diphtheria...</u>
<u>424</u>	Verfaillie	rDNA	19-SEP-03	19-SEP-03	<u>Correction of FANCC gene ...</u>
<u>425</u>	O'Sullivan	rDNA	19-SEP-03	19-SEP-03	<u>Analysis of bacteriophage...</u>
<u>426</u>	Peterson	BioTox	22-SEP-03	22-SEP-03	<u>The role of mycotoxins-a...</u>
<u>427</u>	Diebold	rDNA	30-SEP-03	30-SEP-03	<u>Mechanism of Transforming...</u>
<u>429</u>	Reed	rDNA	30-SEP-03	30-SEP-03	<u>Genetic Linkage map for t...</u>
<u>433</u>	thayer	rDNA	30-SEP-03	30-SEP-03	<u>Modulation of Calcium Sig...</u>

Generate Continuing Review Labels

IBC Meeting Minutes

12/04/03 1-3 pm

W-162 Boynton

Those attending: Peter Southern, Jim Lauer, Melissa Nellis, Claire Kari, Ann Fitzpatrick

It was agreed to prepare a meeting for January 5th and set up meetings for the 1st Monday of the month

Any feedback from the letter to David Hamilton?

None

a letter from a contingent of those involved will be sent explaining the scope of the problem and the anticipated needs for securable facilities in the near future

Adrienne Baranaukus from Fairview has said they have a researcher who is ready to fill out a proposal for submission to our Institutional Biosafety Committee

when may we begin to accept proposals :as soon as their members are approved by NIH

when do we begin inviting them to meetings: as soon as their members are approved by NIH

they have provided a Fairview specific front page to the submission form

Transgenic animals as raptor food

NIH guidelines appear to prohibit feeding transgenic rodents to raptors we anticipate prohibiting the feeding of transgenic rodents in the near future

we will inform the raptor center and the RAR and give them time to respond before we set policy

Oversight of Paul Orchard project

Any adverse events will be reported to the committee

any major changes to the protocols will be reported to the committee

experiments and animals

implementation of notification

Claire and Melissa will try to identify how many labs are using animals and how they are being housed

DNA vaccines

NIH wants the IBC approval on these proposals

we have one proposal and IACUC just received another asking to test a DNA vaccine

It was agreed that we will provide educational materials to the full membership at the next meeting

this will serve two purposes: provide the committee with the information and document training of committee members (an NIH requirement for an IBC) Members will

IBC Minutes

1-3

rm 126

~~JAN 27th~~ -
JAN 5th, 2004

Members Present:

David Brown, Ann Fitzpatrick, Cynthia Gillet, Claire Kari, James Lauer, Melissa Nellis, Peter Southern, Mary Anne Sullivan, Michael Verneris

Members Absent:

John Hunt, Michael Sadowsky, David Somers, Chester Whitley

Guests:

Adrienne Baranaouskas, Kevin Mayo and staff

- I. Report on response to letter to David Hamilton
Response from David Hamilton
IBC response to response or lack of response

Dr. Hamilton has received the letter but is unable to comment at this time

- II. Fairview says they will have a proposal to submit to our IBC soon
they may do so as soon as NIH approves their two members
to our IBC

Adrienne Baranaouskas from Fairview attended the meeting as an ex Officio member and will provide CV's for Fairviews members before the 14th of Jan. They will invited to meetings as soon as NIH approves their participation.

- III. Transgenic animals as raptor food
NIH guildlines appear to prohib feeding any transgenic animal to another animal for food although they only consider the use of transgenic farm animals as food, rodents probably apply

The IBC will contact the Raptor center and the RAR
to discuss the problem before setting a policy

*The IBC passed a motion to no longer feed raptors transgenic or knockout mice.
Dr. Redig will be informed of the committee's decision.*

- IV. Oversight of the Paul Orchard project
This is a human subjects project approved by our IBC
and I will inform the
the IBC committee of any adverse events or other

*The committee was reminded about the human subjects projects overseen by the committee and that records must be kept forever.
communication from the study*

- V. BL2 experiments and animals
Roland Gunther and Cyd are notified whenever a proposal is approved that includes animals to be kept at

Melissa and Claire are looking for a way to link the ordering of animals and notification to RAR about where they should be housed because approvals are for 3 years and animals may be ordered at anytime after approval

The number of studies at and using animals that have been approved are 146 using mice &/or rats, chinchillas, rabbits. 18 use large animals (dogs, or pigs, or cattle, or turkeys) 4 use human subjects

An effort will be made to add notification of safety level to the ordering process so that animals are flagged at the time of purchase

- VI. Proposals that have been approved since the last IBC meeting

The committee was given the list and titles of administrative approvals since the last meeting and is comfortable with the majority of proposals being given administrative approval rather than approval by the full committee.

The committee wants to encourage electronic submission of proposals and an effort will be made by the coordinator to make easier for the client to do so.

- VII. Educational and Training material
NIH requires that IBC's have ongoing training and education of their members. Please keep these materials.

DNA vaccines

NIH wants IBC approval of these projects

The IBC has approved one for Pat Redig to study the efficacy of a West Nile Virus vaccine in Japanese Quail
Included in your packet are several handouts describing DNA vaccines

Also included in the packet is a reprint about Vector vaccines and how they work and who is testing them

- VIII. Dr. Mayo is invited to attend the meeting to discuss his work with classII pathogens in

Dr. Mayo attended the meeting with two staff members and answered the committee's questions, he will be sent a follow up letter listing the information the committee would like added to his proposal before it is approved.

I. Study #473 , ""

Dr. Skinner is invited to the meeting to discuss her work with SIV and HIV tissue.

Dr. Skinner did not attend the meeting and Jim Lauer will visit her lab before approval is given.

IBC Minutes
April 5th 1-3 2004
N101 Boynton HS

Members Present:

Adrienne Baranaouskas, David Brown, Ann Fitzpatrick, Cynthia Gillet, Christine Hendrickson, John Hunt, Claire Kari, James Lauer, Melissa Nellis, Carol Risdal, Michael Sadowsky, Peter Southern, Mary Anne Sullivan, Michael Verneris, Chester Whitley

Members Absent:

Roland Gunther, Jeff Perkey, David Somers

Guests: none were invited

New members Christine Hendrickson, and Carol Risdal were introduced to membership

I. Study 537 Marie Gramer

'Evaluation of Protective Immunity Induced By Intramuscular Vaccination With Inactivated H1N1 and H3N2 Bivalent Swine Influenza Virus (Pfizer FluSure) Vaccine After An Intranasal Challenge Of Pigs With A Recent Field Isolate Of H1N1 Swine Influenza Virus'

Ask Dr. Gramer for an SOP for disposal of all protective gear, post sacrifice of the animals and for an exposure SOP, ask how carcasses are transported across the street.

II. Study 541 Saltzman, Daniel

Anti-tumor Mechanisms of Attenuated Salmonella typhimurium, with and without Interlukin-2, in a mouse model of metastatic cancer

The work will be approved when the protocols are changed to reflect requirement that all animal work is done in and gavage will be done in a biosafety cabinet, tissue harvest will be done in a biosafety cabinet and the committee will be provided with antibiotic sensitivity data.

III. Study 542 Saltzman, Daniel

Anti-Tumor Mechanisms of Attenuated Salmonella typhimurium with and without Interlukin-2, in

IV. Study 493 Njenga, Kariuki

Mouse Models of Viral Zoonosis: Risk of Host-to-Host and Graft-to-Host Virus Transmission

Ask Dr. Njenga if a substitute for the human pathogen, coxsackie B virus can be found, ask what is meant by "periodic screening", a part of his safety protocols. Stipulation made that all animal work is done under

V. Response from David Hamilton

An annual safety commentary will be written and given to Dr. Hamilton

VI. Will the IBC require biosafety cabinets being used for BL2 work to be certified annually?

A policy will be drafted and presented to the committee at the next meeting for approval

VII. IBC practice regarding USDA/APHIS approved projects, no transgenic work done here, plants are made elsewhere, grown here in field trials in U of M owned fields

Tabled until the next meeting

VIII. HHS visit to the campus on April 13th

The visit lasted two days and the exit report was very favorable, a full written report will be sent to us in about 6 weeks.

**IX. Educational opportunities
BSL3 Seminar Series Emory
Gene Therapy Conf. Mpls**

**X. What is new in the IBC office
without computer support temporarily
a scanner has been purchased
response to electronic submission of forms positive
Labs are visited annually and as part of the visit they are asked for their
SOP's and IBC approval # and date**

XI. Call to members to suggest items to included in the search fields of the IBC database

XII. list of administrative approvals since the last meeting

IBC Minutes

Monday May 5, 2004 1-3 PM
N1001 Boynton Health Service

Members Present:

Adrienne Baranaouskas, David Brown, Ann Fitzpatrick, Cynthia Gillet, Christine Hendrickson, John Hunt, Claire Kari, James Lauer, Melissa Nellis, Carol Risdal, Michael Sadowsky, David Somers, Peter Southern, Mary Anne Sullivan, Michael Verneris, Chester Whitley

Members Absent:

Roland Gunther, Jeff Perkey

Guests:

Dr. Scott Fahrenkrug and Dr. Saltzman, et. al

- I. **Ratify minutes of last meeting and note that there are two invited guests**
 - o Invited guests are Dr. Scott Fahrenkrug (1:30-2:15) to discuss Sleeping Beauty transposon and his proposal, and Dr. Saltzman (2:15-3:00) to discuss the committee's stipulations for approval of his proposal

Dr. Fahrenkrug and Dr. Saltzman did attend the meeting. Dr. Saltzman was accompanied by 3 members of his lab group.

- II. **IBC policy covering the certification of biosafety cabinets used for experiments**
 - o Any procedures done in a biosafety cabinet will be done in biosafety cabinets that have been certified within the past year.

Policy will be drafted and sent to the committee members to review at a later date but before the next meeting.

- III. **IBC practice regarding USDA/APHIS approved projects that have the transgenic work done elsewhere, plants propagated elsewhere and transgenic plants are grown here in field trials in U of M owned fields**

- o should we ask them to submit a proposal (even though they technically do not have to) because of the nature of the work and the high profile of any activities involving GMO's

Anytime recombinant material is on campus, it must be registered with the

IBC. An IBC form does not need to be filled out if the researcher can provide a copy of APHIS/USDA approval. Proteins do not need to be registered with the IBC.

IV. Call to members to suggest items to included in the search fields of the IBC database

- o Getting search fields added to the IBC database is a very lengthy process and one that is done by the JAWS group. If there are any suggestions for essential search fields please suggest them. At present it is possible to search for all rDNA studies, all IA studies, all BT studies, studies involving animals and at what safety level

no new search fields were suggested.

V. Report on the HHS visit to campus on April 13th and 14th.

- o the visit lasted two days and the exit meeting report was very favorable, a written report will be sent in about 6 weeks.

VI. Dr. James McCarthy

- o He wants to use Adenovirus in practice in the lab and keep his animals at _____ He also seeks approval to _____

Problems with labs in will be discussed at an executive meeting and a compromise sought.

VII. Dr. Haase lab

- o Dr. Haase is studying scrapie samples. They wish to test whether any previously cloned RNA sequences from purified scrapie agent will promote the conversion of PrPsen to PrPres in the RNA dependent in vitro amplification reaction

IBC committee voted to approve the proposal

Only Steve W. works with prions, Biosafety technician will be asked to visit the lab.

VIII. Dr. Fahrenkrug's SB work

- o Invited expert and guest 1:30-2:15

IX. "Sleeping Beauty Transposition: Biology and Applications for Molecular Therapy" Zsuzanna Izsvak and Zoltan Ivics, Molecular Therapy vol.9, No.2 Feb.2004

supporting information for the discussion of SB

X. Dr. Saltzman's lab

- o Dr. Saltzman has been invited to the meeting to discuss the stipulations placed on his IBC proposal approval. He takes exception to the stipulations and wishes to convince the committee that they are not relevant.
- o Dear Dr. Saltzman,
The IBC proposals ref. above were discussed at the IBC meeting held on April 5, 2004 at length.
It is the committee's decision that the following stipulations must be met before approval is granted:
 1. All animal work will be done in
 2. Gavaging of animals will be done in the biosafety cabinet in
 3. Necropsy and tissue harvest will be done in the biosafety cabinet in
 4. Provide a SOP describing the decontamination procedures to be followed after using a biosafety cabinet
 5. Please provide antibiotic sensitivity data.
 6. For Infectious Agent proposal #542 provide a research summary that clearly states what will be done with each construct. It is not clear whether GFP and IL2 will be used together or separately.

Please respond in writing (response may be emailed, mailed or faxed) to each stipulation before the May 3rd IBC meeting.

You may discuss your proposal at the next IBC meeting on May 3rd from 1-3 in room N101 Boynton HS, if you wish. Please contact me if you will be attending the meeting.

The IBC committee, as a concession to the absolute requirement for prompt handling of the tumor cells, approves the tumor work to be done in the lab, gavaging mice with bacteria will be done in in a biosafety

cabinet, biosafety cabinet will be certified, mice will not be kept in the lab for more than 12 hr., approval only relates to experiments done with mice.

o

XI. Dr. Saltzman's companion proposal

- o companion proposal same stipulations

The IBC committee , as a concession to the absolute requirement for prompt handling of the tumor cells, approves the tumor work to be done in the lab, gavaging mice with bacteria will be done in in a biosafety cabinet, biosafety cabinet will be certified, mice will not be kept in the lab for more than 12 hr., approval only relates to experiments done with mice.

IBC MINUTES
June 7, 2004
1-3 pm
Rm. 126 Boynton HS

Members Present:

Adrienne Baranauskas, David Brown, Ann Fitzpatrick, Cynthia Gillet, Roland Gunther, Christine Hendrickson, John Hunt, Claire Kari, James Lauer, Melissa Nellis, Carol Risdal, David Somers, Peter Southern, Mary Anne Sullivan, Michael Verneris, Chester Whitley

Members Absent:

Jeff Perkey, Michael Sadowsky

Non voting members who were present:

Melissa Nellis, Adrienne Baranaukus, Claire Kari, Roland Gunther

Guests:

Xiaohong Chen, Ulrike Munderloh, Gerry Baldwin, Peter Raynor, Tom Kuehn

- I. Minutes of the May 3, 2004 meeting for ratification
- II. Dr. Ulrike Munderloh and Dr. Gerry Balderidge are here to discuss their request to change their protocols. (1 pm)

Changes to their proposal were approved.

- III. McCarthy compromise for plus work in
Wording of statement was discussed and precedent approved.

III. Biological Safety cabinet policy

Biological Safety Cabinets in laboratories and animal care facilities approved for experiments must be tested and certified annually by a qualified service person.

The policy was sent to the IBC membership via email, voted on and approved unanimously by the 10 respondents. (a quorum is 8)

IV. Raynor proposal # 589 Integrated Biological Data From filter Samples in Buildings

The committee stated their concerns and recommended revision and resubmission of the proposal.

V. Report on the Animal Containment (BL2) and report on actions at other Big 10 Universities

The committee complimented AF on her excellent work and exploration of the topic will continue.

VI. U of M to lead national effort in Food Agro-Security

DB has attended a training session on the Food Agro-Security initiative and could report that little wet lab work will be done at this university so involvement of the IBC will be small.

U of M to Lead National Effort in Food Agro-Security

See meeting packet for a copy of the press release. Do you anticipate any impact on the IBC?

IBC MINUTES

Aug. 2, 2004

1-3 pm

Rm. 126 Boynton HS

Members Present:

Adrienne Baranauskas(NVM), David Brown, Ann Fitzpatrick, Roland Gunther (AV), Christine Hendrickson, Claire Kari (NVM), James Lauer, Melissa Nellis (NVM), Carol Risdal, Michael Sadowsky, Peter Southern, Mary Anne Sullivan (C) Michael Verneris, Chester Whitley

Members Absent:

Jeff Perkey (NVM), Cynthia Gillet (AV), David Somers, John Hunt (C)

Guests:

Dr. Patricia Tam

I. Minutes of the June 7,2004 meeting for ratification

The minutes were ratified and a decision was made to let the minutes reflect the entire meeting content because IBC meetings are free and open to the public.

II. Patricia Tam Proposal 602 and 603 (6 files)

"Viral dsRNA as a Mediator of Chronic Muscle Disease"

Dr. Tam will attend the meeting and 602 and 603 are companion proposals. She proposes to use coxsackievirus B as part of her protocol. This is a renewal of 2K269.

Dr. Tam met with the committee and answered the committee's questions. Her proposal was approved with the condition that RAR be notified when re-implanted experiments are completed in the MGL.

III. Kim-Sue R. S. Tudor proposal 592 (8 files)

1. "The role of TSLP in B-lymphopoiesis" 2. "Mechanisms Governing T-helper cell Differentiation" 3. "A Murine Model of Human Malignant LCH" (three titles)

Dr. Tudor wishes to conduct level work in

Dr. Tudor's proposal was discussed and there are several questions that could not be answered from the documents submitted.

Questions will be sent to Dr. Tudor:

*What are the cytokines to be used and are there safety considerations associated with their use?
STAT 5 is an oncogene please explain what safety precautions will be used in these experiments
what are the associated risks and how will staff be protected?*

TSLP is thymic stromal cell derived lymphopoietin a protein receptor, what risks, if any, are associated with its use?

Will any more staff be working on the projects ?

Why can this work be safely done in

Jim Lauer was asked to visit the lab and Dr. Tudor to inspect the facility and discuss the proposal and if [BSL1 PLUS SPECIAL PPE'S] research may be conducted.

VI. Michael Farrar proposal 604 and 605 (1 file contains both protocols) "Regulation of Suppressor T cell development by STAT 5"

Dr. Farrar wishes to conduct level work in and these are companion proposals.

Dr. Farrar's proposal was discussed by the committee and the project was approved with following condition : Jim Lauer will visit the lab and inspect it before approval is given and the approval is only for in vitro work. If the PI adds an in vivo component to his experiments he must seek approval for the work with additional communication . Jim Lauer will visit his lab and inspect the facility and decide if [BSL1 PLUS SPECIAL PPE'S] may be done in his lab space.

V. McCarthy compromise provided for review

5-4-04 (McCarthy compromise)

1) are defined by a fairly rigid interpretation of the CDC/NIH 4th Edition Guidelines. This would include a closed work area that is truly restricted to those workers actively and continuously connected to the project. If the description of is changed in the 5th Edition, then that would be the time to adopt modified U of MN interpretations.

2) In situations as represented by Jim McCarthy, relating both to the organization of the lab space AND the specific experiments to be performed, we designate a [BSL1 PLUS SPECIAL PPE'S] category wherein all procedures comply with regulations but there is the required compromise of the "rope" to restrict access to the working area. Under plus conditions, hoods, centrifuges and microscopes are located as far away as possible from any communal areas and incubators and freezers are conspicuously labeled

Jim McCarthy would qualify for PLUS SPECIAL PPE'S] by virtue of his end lab and the replication incompetent adenovirus.

3) Another hypothetical investigator, Dr X, with lab space in the middle of who wants to clone oncogenes and growth factors into replication competent adenoviruses would be held to the higher standard of complete

... will be called [... SPECIAL PPE'S] to highlight the special precautions.

VI. Animal Housing Issues

Provided below is a letter Dr. Gunther has sent out to researchers with a vested interest in the outcome of any decisions. Ann and Melissa will present more information for the committee to consider.

Animal housing issues were discussed and a group of PI's will provide their suggestions to the IBC. Chet Whitley and Roland Gunther will meet with a program project group and gather more input on the topic.

VII. Informational items

List of proposals approved since the last meeting

IBC MINUTES
Sept.13th, 2004
1-3 pm
Rm. 120 Boynton HS

Members Present

Adrienne Baranauskas(NVM),	David Brown,	Ann Fitzpatrick,
Roland Gunther (AV),	Claire Kari (NVM staff),	James Lauer,
Melissa Nellis (NVM),	Carol Risdal,	Michael Sadowsky,
Peter Southern (Chair),	Mary Anne Sullivan (C)	Michael Verneris,
Chester Whitley,	David Somers,	

Members absent

Felicia Mroczkowski (NVM), Jeff Perkey (NVM), Cynthia Gillet (AV), John Hunt (C),
Christine Hendrickson,

Invited guest(s)

Dr. Kim-Sue Tudor (1:20pm) cancelled her appearance
Dr. LiLian Yuan (1:45) met with the committee

The Meeting Schedule for the year is included in the packet

I. Minutes of the Aug.2, 2004 meeting for ratification

A motion was made to approve the minutes and carried.

II. Kim-Sue R. S. Tudor proposal 592 (8 files)

1. "The role of TSLP in B-lymphopoiesis" 2. "Mechanisms Governing T-helper cell Differentiation" 3. "A Murine Model of Human Malignant LCH" (three titles)

Dr. Tudor was invited to the meeting and chose not to attend.

Dr. Tudor wishes to conduct level work in Dr. Tudor has replied to the questions that were sent to her after the last meeting. Her reply is included in the materials from her lab. Jim has also visited Dr. Tudor's lab and talked to her. She shares a lockable tissue culture room with Dr. Farrar and will do the proposed work in there.

The committee agreed that it is not possible to approve the proposal as it is presented. It has been put it on the Oct. 4th Agenda and the committe provided questions to be given to

Dr. Tudor before the meeting. Jim Lauer and I will also try to schedule a meeting with Dr. Tudor to discuss her proposal and what questions need to be answered.

III. LiLian Yuan proposal

“Molecular mechanisms of dendritic K channel function” and Dendritic ion channel trafficking in plasticity”

Dr. Yuan is invited to the meeting and is scheduled at 1:45, she does not have a biosafety cabinet and doesn't want to buy one for a short term experiment. She does have a chemical fume hood. She also would like to keep animals in her lab for 3 days.

Dr. Yuan met with the committee agreed to the following conditions

No more than 10 mice will be kept in the lab at one time, they may be kept in the fume hood, no chemicals will be stored with the mice, the IBC will be informed when staff are added to the lab and Dr. Yuan will supervise their training in practices. Dr. Yuan will explain how the virus is titered and her reply is below.

Since the recombinant virus can initiate only one round of infection, the titer of the packaged stock cannot be determined by a conventional plaque assay. However the amount of recombinant virus needed for high level expression can be determined empirically by performing an expression experiment using dilution of virus. Here is the procedure.

BHK cells will be cultured and plated in tissue culture dishes. Different dilutions (1:10, 1:100 etc) of the virus stock will be used to infect cells and the heterologous protein expression is detected by either GFP or antibody against the protein. The percentage of cells that score positive for fluorescence multiplied by the dilution factor gives the virus titer. According to our previous experience, the titer usually falls in the range of 10^8 to 10^9 /ml.

IV. Report on visit to Michael Farrar's lab and his proposal 604 and 605 (no files)

“Regulation of Suppressor T cell development by STAT 5”

Dr. Farrar wishes to conduct work in Jim visited Dr. Farrar's lab and can verify that he has a lockable tissue culture room for the proposed work. His proposal was given IBC approval. He was also cautioned that the approval is for *in vitro* work only.

V. Henry Balfour proposals 636 and 637 (2 pdf files)

636 “1. AIDS Clinical Trials Unit

2. Infectious Mononucleosis Protocol 2A Randomized Study Assessing Antiviral Activity and Safety of Valacyclovir in Primary Infectious Mononucleosis”

637 “Whole Virus Competitive HIV-1 Fitness Assay Using GFP Reporter Virus Ranks Replicative Capacity of X4 vs. R5 Viruses”

Jim has worked with Dr. Balfour during the 30 plus years that he has been at the U and Jim can attest to the care with which research is conducted.

VI. Ed Hammond article: an informational article describing the “Sunshine Project” review of IBC’s around the world.

This is a copy of the article that appeared in Science Magazine and our IBC was reviewed by the Sunshine Project. We sent the Project copies of the minutes from two meetings after review of the minutes by University lawyers.

VII. Does anyone have anything to report about the safety level of various viral vectors currently in use by the U community?

An investigative committee is researching the problem and will report sometime in this winter.

The problem of appropriate space was also discussed and a letter will be drafted to officials at the University with control over building design.

VIII. List of proposals approved since the last meeting

NOTE: Every item on the list will look like a link on a computer screen but none of the links will work on your computer.

IBC MINUTES
OCT. 4th, 2004
1-3 pm
Rm. 126 Boynton HS

Member Present

Adrienne Baranauskas(NVM),	David Brown,	Ann Fitzpatrick,
Felicia Mroczkowski (NVM)	Roland Gunther (AV),	Claire Kari (NVM staff),
James Lauer,	Melissa Nellis (NVM),	Peter Southern (Chair)
Mary Anne Sullivan (C)	Michael Vemeris,	Cynthia Gillet (AV),
John Hunt (C),	Carol Risdal	

Members Absent

, Michael Sadowsky, Chester Whitley, Jeff Perkey (NVM), David Somers, Christine Hendrickson

Invited guest(s)

Dr. Kim-Sue Tudor did attend (1:45 pm)
Dr. Hall and Dr. Vallera did attend (1:10pm)

The Meeting Schedule for the year is included in the packet

Is it possible for meetings to be scheduled for the rest of the year on the 2nd Monday of the month? Change Nov. meeting to Nov. 8th and Dec. meeting to Dec. 13th. Would anyone like to choose a new day and time?

The committee approved the change of the Nov. meeting date to Nov.8th and the Dec. meeting to Dec.13th

I. Minutes of the Sept.13, 2004 meeting for ratification

The minutes were ratified.

II. Kim-Sue R. S. Tudor proposal 592 (8 files)

1. "The role of TSLP in B-lymphopoiesis" 2. "Mechanisms Governing T-helper cell Differentiation" 3. "A Murine Model of Human Malignant LCH" (three titles)

Dr. Tudor was invited to the meeting and will attend. She will arrive at 1:45

Dr. Tudor has prepared a new proposal for review by the committee. Her original proposal is provided at this time and the new proposal will be added to the meeting packet on the web site separately. The committee will be notified when it is added.

Dr. Tudor was asked to expand her tissue culture protocol and provide comprehensive mouse protocols. She was asked to provide an SOP for the injection of mice that includes sharps procedures and restraint system. She was asked to provide a description of the training she has had with lenti viruses and how much training her staff will get. The safety protocols should be dated. If she decides to clone other genes approval from the IBC must be sought before the work is begun.

III. Xiaohong Wang proposal #650 (3files)

"Myocardial Recovery in Severe Hypertrophied Heart After VEGF Modified Autologous MSCs Transplantation"

Dr. Wang needed IBC approval before Sept. 30. She was given administrative approval contingent upon answering all questions posed by the committee and following all recommendations.

Dr. Wang will be asked to provide a description of the route of administration of cells to the pigs and who will administer the cells. She will be asked to provide SOP's for injecting pigs. She will be asked when her biosafety cabinet will be certified. She will be asked to identify the staff working with her and their training.

IV. Walter Hall proposal # 644 (2-3files)

A Phase I, Single Center, Dose Escalation Study of a Recombinant Fusion Protein Composed of the Amino Terminal Fragment of Urokinase-Type Plasminogen Activator (AT) and a Mutated Form of the Diphtheria Toxin (DT) for the Treatment of Glioblastoma Multiforme

Dr. Hall and Dr. Vallera plan to attend. Dr. Hall has said he will send a revised form to the committee. The original submission referred to the Investigator Protocol to answer most questions (a 55 page document) I have provided the full document and I have extracted the pertinent pages and added them to their form. If they provide a revised document I will provide it as soon as possible. Note: a list of answers to questions I asked is also included with the form

The coordinator was asked to look up Dr. Vallera's IBC proposal with the title "Experimental Brain Cancer" and check that he is approved to make DTAT. The coordinator can report that Dr. Vallera has two IBC proposals covering the making of DTATs. They are #421 Biological Toxin approval and #422 rDNA approval. Dr. Vallera will be asked to update and date his safety protocols and send in the current version. He is also asked to send in a "Patient consent form".

- V. Does anyone have anything to report about the safety level of various viral vectors currently in use by the U community?

Scott McIvor has told Roland he will provide a list of vectors and safety recommendations.

- VI. Feedback from the letter regarding “ Containment Facilities in Open Plan Buildings”

A revised letter will be sent to the committee for review and comments based on the discussion at the meeting.

- VII. Yogi Shimizu #660 “PI 3- kinase gamma and T cell-mediate anti-viral responses

The committee asked that Dr. Shimizu clarify the injection site described in the protocol. They asked that he be informed that RAR will write the protocol to be followed in the mouse room and it will be followed by all staff.

- VIII. List of proposals approved since the last meeting

NOTE: Every item on the list will look like a link on a computer screen but none of the links will work on your computer.

IBC MINUTES
NOV 8, 2004
1-3 pm
Rm. N101 (library) Boynton HS

Member Present

David Brown,
Claire Kari (NVM staff),
Peter Southern (Chair),
Cynthia Gillet (AV),

Ann Fitzpatrick,
James Lauer,
Mary Anne Sullivan (C)
Carol Risdal

Christine Hendrickson,
Melissa Nellis (NVM),
Michael Verneris,
Chet Whitley

Members Absent

Michael Sadowsky, Jeff Perkey (NVM), David Somers, Roland Gunther (AV), John Hunt (C), Felicia Mroczkowski (NVM), Adrienne Baranauskas(NVM),

Invited guest(s)

Dr. Jason Lilly, Invitrogen

The Meeting Schedule for the year is included in the packet

Please provide Claire with your preferences for a meeting time.
Will scheduling it for the 2nd Monday of the month from 1-3 work for everyone?

I. Minutes of the Oct.4, 2004 meeting for ratification

The minutes were ratified.

II. Educational event Jason Lilly invited guest

Presentation and discussion of viral vectors

'Differences in Safety Features of Viral vectors'

Followed by a Q&A session.

Jason Lilly, PhD

Technology Specialist-Midwest

Invitrogen Corp

Dr. Lilly gave a very interesting presentation and members requested that they be sent a copy of the power point presentation. Peter will draft a letter and send it to Dr. Lilly and Mr. Mark Heckathorne describing the information the committee would find most useful from Invitrogen.

III. Kim-Sue Tudor revised proposal

Dr. Tudor's proposal was approved by the committee for the in vitro portion of her proposal only. If she adds in vivo work she must seek and receive prior approval from the IBC.

IV. Pam Skinner #661 (3 files)

Gene expression alterations and the pathogenesis of prion diseases

List of Dr. Skinner's proposals that are approved

260 Artificial Gene Transfer and Recombinant DNA DNA Microarrays to Diagnose Transmissible Spongiform Encephalopathies

293 Artificial Gene Transfer and Recombinant DNA Gene Expression Alterations During Prion Disease

446 Artificial Gene Transfer and Recombinant DNA DNA Microarrays to Diagnose Transmissible Spongiform Encephalopathies (Prion Dis...

473 Infectious Agents In situ tetramer staining of tissues from SIV infected macaques and HIV infected...

Dr. Skinner's proposal may be approved administratively if her reply to several questions is satisfactory. The questions are: is sonicating done in the biosafety cabinet?, what are the personnel safety procedures for staff inoculating mice?, how will cages be decontaminated?, the information for emergency medical contacts will be corrected, LpH use on skin as a disinfectant will be replaced by a safer alternative. The BioSafety Officer will review her replies and approve the proposal if warranted.

V. Follow up decontamination and medical response discussion.

Request by Christine for discussion of the topic

VI. Linda McLoon and Stephen Christiansen #672

"Novel Immunotoxin Therapy for Strabismus Treatment"

Administrative approval may be granted upon receipt of Dr. McLoon's response to several questions or comments. 1) Her staff do not need OSHA40 HAZWOPER training, lab specific training is what is needed. 2) why are they doing MTD?

VII. List of proposals approved since the last meeting

NOTE: Every item on the list will look like a link on a computer

screen but none of the links will work on your computer.

INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes **December 13, 2004** **1-3 pm** **Rm. 126 Boynton HS**

Executive Meeting

Ann Fitzpatrick Claire Kari (NVM staff) James Lauer Melissa Nellis (NVM) Peter Southern (Chair)

Those present

Ann Fitzpatrick Claire Kari (NVM staff) James Lauer Melissa Nellis (NVM) Peter Southern (Chair)

The Meeting Schedule for the year 2005 is included in the packet

Please provide Claire with your preferences for a meeting time.

Carol would prefer a Tuesday or Wednesday meeting day

I. -- policy statement

A policy statement will be prepared and sent to the committee for review and comment. After review and approval by the committee it will be sent to David Hamilton and Timothy Mulcahy, the new VP of research (professor of pharmacology and associate dean for the biological sciences in the Graduate School at the University of Wisconsin-Madison, has been named the new vice president for research at the University of Minnesota. His appointment is effective Feb. 1, 2005, pending approval by the board of regents)

An annual safety audit will also be sent to the VP for Research.

II. Replacement for Dave Somers, plant expert

Jim has a list of possible replacements and is contacting them. He hopes to find a researcher with experience with USDA approved field trials who would be willing to serve on the committee.

III. Meeting Schedule for next year

Monday afternoons appear to be the best fit for the committee members

INSTITUTIONAL BIOSAFETY COMMITTEE

IV. Safety Show and Seminars an IBC educational event

The executive committee proposes that the IBC host an educational event that is a safety product show with mini safety seminars. U Stores, Fisher Scientific and the IBC would be co sponsors. Fisher and U Stores would arrange and pay for the event, the IBC staff would give several seminars and find seminar speakers on relevant topics. The event is planned for late Feb. or Mar. The IBC staff will help with advertising and encourage the RSO's (research safety officers) to attend.

V. NIH proposed review of IBC's

NIH has sent out a memorandum informing IBC's that "the NIH will be conducting site visits at selected institutions to obtain further information on IBC compliance with NIH guidelines and to educate institutions about requirements that apply to the conduct of rDNA research."

Our IBC staff will be reviewing the guidelines and insuring that we can document our full compliance with the NIH guidelines.

Inform the new VP of research of what NIH expects from the institution.

To Do list

We have had no feedback from the Office of Inspector General. Call and ask for the findings of our review that was conducted by the Office of the Inspector General last spring.

Set up a file of material describing our interactions with Regulatory Agencies

Make a list of the meetings IBC members have attended as part of their duties as an IBC member for the NIH compliance documentation

Schedule an annual safety audit on the IBC calendar and that the results be sent to the VP of research

Inform the new VP of research of what NIH expects from the institution.

Put a description of the plan of the new Translational building on the next IBC agenda

Hi All,

Here is an updated list of the dates for meetings in 2005. Meetings are at 1-3 pm at Boynton HS and will be in room 126 when the room is available.

MEETINGS ARE ON THE SECOND MONDAY OF THE MONTH IN 2005

Any date, of course, may be changed if there are conflicts, so please keep me informed if you need a date changed.

Monday December 13th

Monday January 10th - CANCELLED - NOT ENOUGH WORK

Monday February 14

Monday March 14

Monday April 11

Monday May 9

Monday June 13

Monday July 11

Monday August 8

Monday September 12

Monday October 10

Monday November 14

Monday December 12

Please reserve these dates on your calendars.

INSTITUTIONAL BIOSAFETY COMMITTEE
OF PREVENT PROTECT

MINUTES
FEBRUARY 14, 2005
1-3 pm
Rm. 126 Boynton HS

Members Present

David Brown	James Lauer (BSO)	Adrienne Baranauskas(NVM)
Ann Fitzpatrick	Gary Muehlbauer	Claire Kari (NVM staff)
Roland Gunther (AV)	Carol Risdal	Melissa Nellis (NVM)
Christine Hendrickson	Chester Whitley	
John Hunt (C)		

Member(s) Absent

Mary Anne Sullivan (C), Peter Southern, Michael Sadowsky, Michael Verneris,
Cynthia Gillet (AV)

Roster of 13 members(quorum equals 8). 9 members attending

Invited guest(s)

none

The Meeting Schedule for the year 2005 is included in the packet

I. Minutes of the Nov.8, 2004 and Dec. 13 meeting for ratification
The minutes were ratified without any changes

II. Introduction of our new member

Dr. Gary Muehlbauer from the Dept. of Agronomy and Plant Genetics is
replacing David Somers as our plant expert
Dr. Muehlbauer was introduced to the committee.

UNIVERSAL BIOSAFETY COMMITTEE

PREVENT PROTECT

III. Dr. Jameson's addendum to his protocols for use of the "Pathogen Room" on

Administrative approval may be granted as soon as Dr. Jameson agrees to implement the 4 stipulations of the committee. The stipulations are 1) specify the dilution rather than the % bleach that will be used for disinfection. 2) If vaccinia infected animals are in the room no unvaccinated person may enter 3) no reuse of disposable lab coats used for work with vaccinia.

A copy of the addendum is provide in the meeting packet
The relevant sections from the NIH guidelines are provided for reference

http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_G.htm#Toc7246567

Appendix G-II-B-2. Special Practices (

Appendix G-II-B-2-a. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.

Appendix G-II-B-2-b. The Principal Investigator limits access to the laboratory. The Principal Investigator has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.

Appendix G-II-B-2-c. The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.

Appendix G-II-B-2-d. When the organisms containing recombinant DNA molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universal biosafety symbol is posted on the access door to the laboratory work area. The hazard warning sign identifies the agent, lists the name and telephone number of the Principal Investigator or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.

INSTITUTIONAL BIOSAFETY COMMITTEE

PREPARE PREVENT PROTECT

IV. Dr. Yoji Shimizu "Very late antigen integrin activity on T cells" Biological Toxin proposal IBC # 709

Dr. Shimizu is to be asked if he has considered alternatives to SEE

His reply:

We have considered alternatives to SEE. However, we are studying antigen-specific activation of a human T cell line, Jurkat. We need to use this cell system, as the mutant derivatives that we have created in this cell line are unique cellular reagents that are not available in another cell system. The only available methodology to activate the antigen-specific T cell receptor expressed on Jurkat T cells in a physiologically relevant way is to use SEE. We have used antibodies that non-specifically activate the T cell receptor in previous experiments, but they do not accurately replicate the signaling responses that are observed when these cells are activated with SEE. Therefore, we do not have an alternative to SEE for these experiments.

A copy of the proposal is included in the meeting packet. Dr. Shimizu has also responded to several questions and his response is given below

I am responding to your request regarding my laboratory's proposed use of staphylococcal enterotoxin E (SEE). The toxin (SEE) will be stored in a locked cabinet in _____ All regulations involving the use of Exempt Quantities of Select Agents will be followed. The maximum amount of toxin to be purchased or stored at one time will be 100 micrograms. A toxin inactivation report will be sent to Darlene Charboneau when use of the toxin is discontinued and any remaining toxin is inactivated. Finally, complete records of the amount of toxin used and how it has been inactivated after use will be kept.

V. Dr. Eric Newman "Glia-Neuronal Interactions in the retina"

A copy of the proposal is included in the meeting packet. The protocol was approved by the Biosafety Officer and is provided to keep the Committee informed about toxin research on campus.

Dr. Newman is to be asked if all staff will be vaccinated before they work with tetanus toxin. Darlene has visited their lab recently, checked over their SOP's and they are well written and in use in the lab. She found no problems with the lab, they have good lab space and the lab is well run.

VI. NIH proposed review of IBC's

A review of our program by the coordinator is underway and close attention is being paid to the NIH guidelines and communications from NIH during the last year

INTERNATIONAL BIOSAFETY COMMITTEE

PREPARE PREVENT PROTECT

VII. Safety Show and Seminars: An educational event

The biosafety group meet with Steve Keeney from U stores, Sue O'Brien from Fisher and several reps of safety products to discuss the show. It was stressed that the seminars will be general talks and not infomercials. The event is scheduled for the week of Mar. 7th. Our contribution will be encouraging anyone working with biological materials to attend. Topics highlighted at the show will be secondary containment for centrifuges, new safety syringes, alternatives to needles, disinfection products, autoclave products and proper use, glove choices, masks etc. The IBC will have a table and so will the biosafety group to answer questions.

The safety show has been rescheduled for the month of June due to problems scheduling vendors and event space.

VIII. List of proposals approved since the last meeting

NOTE: Every item on the list will look like a link on a computer screen but none of the links will work on your computer.

IX. Policy reminder

This policy statement will be added to the IBC web page and sent out to RSO 's

"IBC review and approval is required for research work using attenuated laboratory strains, (including vaccine strains) of pathogenic microorganisms.

Use the Infectious Agent form for IBC submission"

X. BSL2 draft

A draft of the letter was provided to all members of the IBC and members will send their comments directly to Peter who will prepare a second draft of the letter for review by the committee.

INSTITUTIONAL BIOSAFETY COMMITTEE
IDENTIFY PREPARE PROTECT

MINUTES
March 14, 2005
1-3 pm
Rm. 126 Boynton HS

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Adrienne Baranauskas(NVM)
David Brown	Gary Muehlbauer	Claire Kari (NVM staff)
Ann Fitzpatrick	Carol Risdal	Felicia Mroczkowski (NVM)
Cynthia Gillet (AV)	Michael Sadowsky	Melissa Nellis (NVM)
Roland Gunther (AV)	Mary Anne Sullivan (C)	Jeff Perkey (NVM)
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Members Absent Ann Fitzpatrick, Christine Hendrickson, Cynthia Gillet
Quorum = 8, 11 attending

Invited guest(s)

Dr. Eric Hendrickson was encouraged to attend but chose not to attend the IBC meeting.

The Meeting Schedule for the year 2005 is included in the packet

I. Minutes of the Feb. 14, 2005 meeting for ratification

The minutes were ratified without any changes.

II. Henry Balfour IBC proposal # 727(included in packet: proposal)

A5197: A Phase II Double Blind Randomized, Placebo-controlled Study To Evaluate the Antiretroviral Effect of Immunization With the MRK Ad5 HIV-1 GAG Vaccine in HIV-1 infected Individuals Who Interrupt Antiretroviral Drug Therapy

INSTITUTIONAL BIOSAFETY COMMITTEE

PREPARE PROTECT

Committee instructions and questions to be sent to Dr. Balfour

Change wording of safety protocol to state "syringes will be returned to the pharmacy" reagents never leave the pharmacy

The following questions will be asked: 1) How is this vector different from the Penn vector? 2) Is this considered safe because it is a different vector or safe because it is given in smaller doses? 3) Will the range of doses to be used in this trial be the same as the Phase I (toxicity) clinical trial doses?

Dr. Balfour's answers will be sent to Peter and Chet for review before approval is given.

III. Dr. Eric Hendrickson IBC # 725 (included in the packet: correspondence, revised proposal)

- 1. A human somatic cell model for dyskeratosis congenita**
- 2. Ku6 controls DNA repair, telomers and genomic stability**

The committee returned Dr. Hendrickson's proposal for extensive revision.

IV. Is it

Lacking a consensus in the literature the Committee may use either nomenclature.

V. Plan for Translational building (distributed at meeting)

The plans were reviewed by the committee and Jim answered questions about the proposed facility.

VI. Cheat sheet for the NIH guidelines

An educational material for the members of excerpts of content relevant to the IBC to make finding relevant content easier.

VII. Safety Show and Seminars: An educational event

The show will be on June 8th from 10-2 in the BSBE Atrium

INSTITUTIONAL BIOSAFETY COMMITTEE

PREPARE PROTECT

VIII. List of proposals approved since the last meeting

NOTE: Every item on the list will look like a link on a computer screen but none of the links will work on your computer.

IX. Mike Sadowsky proposal and letter

The IBC discussed the proposal and decided that this study is outside the purview of the IBC, however, the IBC would draft a letter to be signed by the Chairman saying the study is following University of Minnesota standards for safe conduct of research

X. BSL2 Letter draft discussion

A final draft was approved and the letter will be sent out the week of Mar. 14th

INTERNATIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

MINUTES

April 11, 2005

1-3 pm

Rm. 126 Boynton HS

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Adrienne Baranauskas(NVM)
David Brown	Gary Muehlbauer	Claire Kari (NVM staff)
Ann Fitzpatrick	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet (AV)	Michael Sadowsky	Jeff Perkey (NVM)
Roland Gunther (AV)	Mary Anne Sullivan (C)	
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Member(s) Absent Cynthia Gillet (AV), Roland Gunther (AV), Gary Muehlbauer, Michael Sadowsky, Mary Anne Sullivan (C),
Quorum equals 7 quorum meet

Invited guest(s)

Dr. Youvraj Sohni #750	1:10 pm
Dr. Eric Hendrickson	
Dr. Yingming Li and Dr. Koeneman	2:30 pm
Dr. McGregor (Dr. Schleiss's co-PI)	1:45 pm
Dr. Belinda Cheung and Dr. Sawchuk	2:00 pm

The Meeting Schedule for the year 2005 is included in the packet

I. Minutes of the Mar. 14, 2005 meeting for ratification

The minutes were approved and ratified with one correction Christine Hendrickson was present and Carol Risdal was absent

II. Henry Balfour IBC proposal # 727(included in packet: proposal)

INSTITUTIONAL BIOSAFETY COMMITTEE

PREPARE PROTECT

A5197: A Phase II Double Blind Randomized, Placebo-controlled Study To Evaluate the Antiretroviral Effect of Immunization With the MRK Ad5 HIV-1 GAG Vaccine in HIV-1 infected Individuals Who Interrupt Antiretroviral Drug Therapy (2 item: vaccine response also given here)

II. Dr. Youvraj Sohni #748 1. FASTMAN: An integrated device for biodefense pathogen detection 2. Integrated devices for biological sample collection and pre-analytic processing (2 items: protocol (pdf and doc) decont. Sheet (pdf and doc))

Dr. Sohni discussed his proposal with the committee. The committee asked Dr. Sohni to provide more information and SOP's.

Write SOP's for handling human feces.

Test Bacillus anthracis Sterne strain for virulence genes before use and document the results.

Write a blood born pathogen SOP that includes protection from aerosols, procedures for dealing with possible viral contamination in clinical samples.

Provide a complete description of the strains that will be used.

Is the E.coli O157:H7 a toxin forming strain, if it is please provide a SOP describing how it will be used.

III. Dr. Stephen Mc Sorley # 746 CD4 T cell response to salmonella: Immune response to bacterial flagellins; In vivo tracking of antigen presentation and CD4 responses to intestinal bacteria (1 item pdf and doc)

Dr. McSorley's proposal was discussed at the meeting and the committee voted to approve the proposal pending specification of the strains being used.

IV. Dr. Stephen Jameson #745 CD8 T cell responses to vaccinia following lymphopenia (1 item pdf)

Dr. Jameson's proposal was approved by the committee.

V. Dr. Eric Hendrickson IBC # 725 1. A human somatic cell model for dyskeratosis congenital 2. Ku6 controls DNA repair, telomeres and genomic stability (3 items: protocol (pdf and doc), letter, decont. page)

The committee was unable to review the proposal as submitted. Dr. Hendrickson declined to meet with the committee. Dr. Southern will try to meet with him before the next IBC meeting to discuss his protocol.

ANIMAL BIOSAFETY COMMITTEE
PREPARE PROTECT

VI. Dr. Mark Schleiss and Dr. Alistair McGregor #741 Molecular Biological Studies of Human and Animal Cytomegaloviruses (2 items: protocol and letter)

Dr. Mc Gregor met with the committee to discuss their proposal and it was approved. Dr. McGregor was instructed to provide the date their biosafety cabinet was or will be certified. This has been done and the date is 11-24-04.

VII. Dr. Sawchuk and Dr. Belinda Cheung #738 A New approach for the Treatment of Otitis Media (2 items: protocol (pdf and doc) and letter)

The committee voted to approve the proposal and animals may be kept at in if blue chucks can be used for the animals waste or they may be housed in the lab.

VIII. Dr. Kenneth Koeneman #744 Further Defining the Role of Potentially Critical Factors Associated with Prostate Cancer Bone Metastasis, Project 1 Synergy Consortium Targeting New Therapies for Lethal Phenotypes of Prostate Cancer (3 items: proposal (pdf), supplement, supplement)

The committee voted to approve Dr. Koeneman's proposal with the condition that his SOP's be edited to delete ref. to other institutions make them specific to practices at Minnesota.

IX. Dr. Kenneth Koeneman #743 Enhancing adenoviral Gene Therapy by Altering the Therapeutic Potency, Project 3 Synergy Consortium Targeting New Therapeutics for Lethal Phenotypes of Prostate Cancer (1 item: proposal (pdf))

The committee voted to approve Dr. Koeneman's proposal with the condition that his SOP's be edited to delete ref. to other institutions make them specific to practices at Minnesota.

INSTITUTIONAL BIOSAFETY COMMITTEE
PREVENT PREPARE PROTECT

X. Safety Show and Seminars: An educational event

The show will be on June 8th from 10-2 in the BSBE Atrium

XI. Mike Sadowsky proposal and letter

XI. BSL2 Letter was sent to Dr. Mulcahy

Dr. Mulcahy will be invited to an executive meeting to discuss the letter in the near future.

XIII. List of proposals approved since the last meeting

NOTE: Every item on the list will look like a link on a computer screen but none of the links will work on your computer.

INSTITUTIONAL BIOSAFETY COMMITTEE
PREPARE PROTECT

MINUTES
May 9, 2005
1-3 pm
Rm. 126 Boynton HS

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Adrienne Baranauskas(NVM)
David Brown	Gary Muehlbauer	Claire Kari (NVM staff)
Ann Fitzpatrick	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet (AV)	Michael Sadowsky	Jeffery Perkey (NVM)
Roland Gunther (AV)	Mary Anne Sullivan (C)	
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Gary Muehlbauer, Michael Sadowsky

Invited guest(s)

Dr. Olhfest	1:15
Dr. Hendrickson	did not attend
Dr. Marc Jenkins	1:50
Dr. Scott McIvor	2:15

The Meeting Schedule for the year 2005 is included in the packet

New business

Ask Dr. Mulcahy for an official response to the letter from the IBC.

Jim was asked to use his contacts to find someone at the CDC to send a written opinion about the Translational building and CDC regulations.

I. Minutes of the April 11th, 2005 meeting for ratification

The minutes were approved

II. Discussion of the Orchard amendment to IBC approval #151

Because of time constraints it was not possible to discuss this at the May 9th meeting

BIOSAFETY COMMITTEE

PREPARE PROTECT

III. Dr. Youvraj Sohni #748 1. FASTMAN: An integrated device for biodefense pathogen detection 2. Integrated devices for biological sample collection and pre-analytic processing

The committee was given an update about t Dr. Sohni's status.

IV. Dr. Elizabeth Pluhar and Dr. Andrew Freese and Dr. John Ohlfest #773 Gene therapy for Canine Brain Tumors

Dr.s Freese and Ohlfest meet with the committee and their proposal was approved with the stipulation that if they begin treating patients they need to file a new approval. They are approved to house the animals at

V. Dr. Eric Hendrickson IBC # 725 1. A human somatic cell model for dyskeratosis congenital 2. Ku6 controls DNA repair, telomers and genomic stability

Dr. Hendrickson was unable to attend. His proposal was approved and he was reminded of the risks of his constructs and potential risk of mutants of those constructs.

VI. Michael Sadowsky # 774 Occurrence and Prevalence of Human Bacterial Pathogens Associated with the nuisance alga Cladophora along Lake Michigan Beaches

Dr. Sadowsky's proposal was approved. He will be asked to provide the IBC office with the date of the biosafety cabinet certification and delete references in his SOPs to orange biohazard bags. He should use autoclaveable waste bags.

VII. Dr. Marc Jenkins #772 Costimulatory signals in CD4+ T cell activation

Dr. Jenkins proposal is approve and he will submit a list of genes to be studied to the IBC office. His animals may be housed at

VIII. Policy review: Risk Assessment of viral vector work and Risk Assessment of animal housing of animals treated with viral vectors

The committee began its discussion of the issue and will deliberate further.

The Pub Med and Medline search results were provided. It was limited to papers published after 2002 and the key words were adenovirus, safety, shedding.

IX. Safety Show and Seminars: An educational event

The show will be on June 8th from 10-2 in the BSBE Atrium

Put the show on as many relevant departmental calendars as possible.

XI. List of proposals approved since the last meeting

INSTITUTIONAL BIOSAFETY COMMITTEE

IDENTIFY PREPARE PROTECT

MINUTES JUNE 13 2005 1-3 pm Rm. 120 Boynton HS

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Adrienne Baranauskas(NVM)
David Brown	Gary Muehlbauer	Claire Kari (NVM staff)
Ann Fitzpatrick	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet (V)	Michael Sadowsky	Jeffery Perkey (NVM)
Roland Gunther (V)	Mary Anne Sullivan (C)	
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Members Absent Gary Muehlbauer, Cynthia Gillet, Michael, Sadowsky
Quorum = 8,

Invited guest(s)

· Dr. Mansky 1 attended at 1:15
Dr. Nagaraja attended at 1:35

The Meeting Schedule for the year 2005 is included in the packet

I. Minutes of the May 9, 2005, 2005 meeting for ratification

**II. Dr. Louis Mansky #778 Molecular analysis of the HTLV-1 GagL
Domain, Mechanisms of HIV variation**

Attended

Four areas of information need to be provided with each proposal

INSTITUTIONAL BIOSAFETY COMMITTEE

PREPARE PROTECT

1. What will be done
2. Why will procedures and protocols be done.
3. How will the project be carried out technically.
4. What safety precautions are needed and how will they be met.

Dr. Mansky will be asked by email for abstracts from his grants and a list of the reagents to be used in his rDNA experiments. Responses will be circulated among members for review.

III. Dr. Kakambi Nagaraja #785 Differential pathogenesis of avian and human metapneumoviruses in turkeys

Dr. Nagaraja and Dr. Halvorson attended.

They will be asked via email for PPE's used during necropsy, SOP's for euthanasia, decontamination agents, confirmation of cabinet certification date. Responses will be sent to the members for review.

IV. Dr. Francisco Diez-Gonzalez #797 Use of Probiotics and Avian Antibiotics for Control of E.Coli)157:H7 in Cattle

Dr. Diez-Gonzalez will be asked via email what strains he will use, he will be asked to keep samples of the strains he uses for the Dept. of Health if there is an accident. Responses will be sent to members for review.

V. A new resource for IBC members: RefWorks account

VI. Policy review: Risk Assessment of viral vector work and Risk Assessment of animal housing of animals treated with viral vectors

A proposal will be drafted by Peter and sent out to the committee for review.

Include Scott McIvor and other researchers when the proposal is circulated.

VII. Safety Show and Seminars: An educational event

The show was held on June 8th from 10-2 in the BSBE Atrium and the response from the University community and vendors was very positive.

VIII. Tularemia outbreak in Boston: an update

Discussed as an important lesson to be learned

The rationale for requiring verification strains thought to be non-infectious strains.

IX. List of proposals approved since the last meeting

X. New Business

Contact Dr. Mulcahy as soon as possible to discuss IBC issues

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

XI. Munderloh addendum

approved

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

MINUTES JULY 18 2005 1-3 pm Rm. 120 Boynton HS

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Claire Kari (NVM staff)
David Brown	Gary Muehlbauer	Cynthia McGill(NVM,IRB)
Ann Fitzpatrick	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet	Michael Sadowsky	Jeffery Perkey (NVM,IACUC)
Roland Gunther	Mary Anne Sullivan (C)	Leslie Pitt-Schneider (NVM)
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Ann Fitzpatrick, Cynthia Gillet, Roland Gunther, John Hunt, Gary Muehlbauer Michael Sadowsky

Invited guest(s)

Dr. Sreervatsan	1:15
Dr. Fleischmann	1:45

The Meeting Schedule for the year 2005 is included in the packet

I. Minutes of the June 13, 2005, 2005 meeting for ratification

The minutes for June 13 were ratified.

II. Dr. Orchard has filed a single patient follow up report IBC #151 and it is on file in the IBC office and is available upon request by a member.

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

III. Dr. Sreervatsan

811 Development of High Affinity Ligands and Methods to detect prions

Approval is granted and he will send us a copy of his USDA/APHIS permit when he receives it.

Add this information to his proposal : Dr. Sreervatsan has 4 years of experience working with prions . .

Dr. Wang has 7 months of experience and was trained by Dr. Sreervatsan

IV. Dr. Fleischmann

821 Novel tumor vaccine for prostate cancer

Write and ask for a description of his project, tell him his abstract from his grant would be acceptable and perhaps the introduction. to the grant. Vaccinia work is not approved for this proposal. He is encouraged to submit a separate proposal if he decides to work with vaccinia.

V. Patrick Schlivert #830,# 831,# 832

Development of Superantigen Antagonists, role of SrrA/B in Gram Positive Bacterial Virulence, Cardiotoxicity of Streptococcal Pyrogenic Exotoxins, Development of Therapeutics for Superantigen-Mediated Diseases

Approved .

VI. Policy review: Risk Assessment of viral vector work and Risk Assessment of animal housing of animals treated with viral vectors

Peter will prepare a policy draft and send it out to the committee for review and consideration.

VII. List of proposals approved since the last meeting

NOTE: Every item on the list will look like a link on a computer screen but none of the links will work on your computer.

VIII. New business

none

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

MINUTES OCTOBER 2005 1-3 pm Rm. 126 Boynton HS

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Claire Kari (NVM staff)
David Brown	Gary Muehlbauer	Carol Siegel (NVM,IRB)
Ann Fitzpatrick	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet (V)	Michael Sadowsky	Leslie Pitt-Schneider (NVM)
Roland Gunther (V)	Mary Anne Sullivan (C)	
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Quorum = 8,
Members absent
Cynthia Gillet (V)
John Hunt (C)
Gary Muehlbauer
Carol Risdal
Ann Fitzpatrick

Invited guest(s)
Peter Southern attended
Peter Bitterman attended

The Meeting Schedule for the year 2005 is included in the packet

I. Minutes of the Sept, 2005, 2005 meeting for ratification

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

II. IBC – proposals for review from 09/12/05- 10/10/05

See complete list on the last page :these were approved

884 Southern

Peter excused himself during the discussion and vote. Mike Sadowsky chaired in his absence.

The committee voted and approved the proposal as written

890 Bitterman

Peter Bitterman and Yong Yean Kim attended and meet with the committee. Prof. trained staff do the injections. Protocol and animal housing was approved at .

894 Argenta

Dr. Argenta's proposal was provided as a hard copy and approved with revision. "Contact BSO after a spill of 10X12" and use of PCR to monitor cleanup will be removed and the nomenclature will be standardized (pfu or vp).

III. Mary Anne's letter to Dr. Mulcahy commenting on open lab formats

Mary Anne sent Dr. Mulcahy another letter reminding him she is still interested in a reply.

IV. Draft of Policy

Work will continue on the policy draft but the final version will not be given to the committee for review until after the report from the auditors.

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

VI. Audit by the Dept of Audits of IBC practices

Claire and Peter gave short reports about their interactions with the auditors. The Committee will be informed about all aspects of the process. The auditors will create a report with "recommended changes" and "essential changes". A copy will be given to the committee and the Regents.

VII. Discussion of housing of animals given viral vectors

Peter prepared a draft of the policy and gave it to the committee for review and comment.

Draft IBC Policy for Animal Housing, 10/10/05.

Mice (animals) injected, infected or otherwise treated in any way with experimental materials generated under conditions (recombinant DNA molecules, recombinant proteins, proteins purified from agents, replication defective viruses or any similar materials) will be housed under containment conditions for 7 days, following the introduction of experimental materials.

Mice (animals) will then be changed into clean cages and housed for the duration of the experiment at

All animal manipulations (retro-orbital puncture, survival surgery, sacrifice and necropsy) performed within the first 7 days will be conducted as procedures.

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The IBC retains the authority to require continued housing of animals at . beyond the initial 7 day period.

PIs may petition the IBC for modified (less stringent) containment conditions for particular experiments but PIs are responsible for presenting comprehensive justifications to the IBC and IBC approval is required before relaxed containment conditions may be adopted.

Animals infected with replication competent agents will be housed under conditions for the duration of the experiment unless the PI presents a compelling argument for housing to the IBC.

VIII. New business

Use of laptops was well received and a suggestion made that power strips be purchased to make plugging in computers safer and easier. Explore loaning the community members laptops for the duration of their appointment to the committee.

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

**<https://in54tst.oit.umn.edu/IN54DEV/IBC> - from
09/12/05 - 11/01/05**

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14 projects found

Project #	P.I.	Project Type	Date	Approved	Summary
<u>880</u>	<u>Marchant, Jonathan</u>	rDNA	13-SEP-05	BSO R	<u>FUNCTIONAL ARCHITECTURE OF IP3-EVOKED LOCAL CA²⁺ SIGNALS CARREER:</u> <u>Application of fluorescent based</u> ...
<u>881</u>	<u>Fallon, Ann</u>	rDNA	15-SEP-05	BSO R	<u>In vitro culture and transformations of Wolbachia from mosquitoes</u>
<u>882</u>	<u>Fallon, Ann</u>	rDNA	15-SEP-05	BSO R	<u>Optimization of Wolbachia production in a mosquito cell line</u>
<u>883</u>	<u>Hsiao Ashe, Karen</u>	rDNA	15-SEP-05	BSO R	<u>The Bioloav of Alzheimer's Disease in Transaenic Mice</u>
<u>884</u>	<u>Southern, Peter</u>	InfAgent	16-SEP-05	Full rev	<u>HIV infection of Human Mucosal Tissues</u>
<u>885</u>	<u>Segal, Yoav</u>	rDNA	16-SEP-05	BSO R	<u>Murine Models of X-Linked Alport Syndrome. Mouse Model of X-Linked Alport Syndrome. Pathobiology of ...</u>
<u>886</u>	<u>Skinner, Pamela</u>	InfAgent	16-SEP-05	BSO R	<u>Impact of alterations in gene expression on scrapie disease pathogenesis and progression</u>
<u>887</u>	<u>Johnson, Joseph L</u>	rDNA	19-SEP-	BSO R	<u>Elucidation of the Structure and Function of Five Mammalian</u>

		05			Beta-secretase Isoforms
888	Wei, Li-Na	21-SEP-05	rDNA	BSO R	TR2 orphan receptor in vitamin A signaling pathway
889	Sadowsky, Michael	03-OCT-05	rDNA	NIH EX 05-OCT-05	A Gene Probe Approach to Determine Sources of Fecal Contamination of Waterways
890	Bitterman, Peter	04-OCT-05	rDNA	Full rev	Role of translational repressor 4E-BP in NRas mediated liver tumor genesis
891	Sanderfoot, Anton	04-OCT-05	rDNA	BSO R	Functional Analysis of Arabidopsis Golgi/endosomal SNARES
892	Gene, Jian-Guo	05-OCT-05	rDNA	BSO R	Endothelial cell biology
893	Bradeen, James	05-OCT-05	rDNA	BSO R	Solanum series Bulbocastana: resistance to late blight and early dying disease

INSTITUTIONAL BIO SAFETY COMMITTEE
 PRESENT PREPARED PROJECT

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

MINUTES **NOVEMBER 14 2005** **1-3 pm** **Rm. 126 Boynton HS**

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Claire Kari (NVM staff)
David Brown	Gary Muehlbauer	Carol Siegel (NVM,IRB)
Ann Fitzpatrick	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet (V)	Michael Sadowsky	Leslie Pitt-Schneider (NVM)
Roland Gunther (V)	Mary Anne Sullivan (C)	
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Members absent

Cynthia Gillet, Chester Whitley, Michael Sadowsky

Attending 11

Invited guest(s)

none

I. Minutes of the Oct 10, 2005, 2005 meeting for ratification

A motion was made to approve the minutes with minor revision and seconded

II. IBC – proposals for review from Oct.10-Nov. 12th

See complete list on the last page

III. Mary Anne's letter to Dr. Mulcahy commenting on open lab formats

The question was asked "is there any new information"? and the answer is there has been no response.

INSTITUTIONAL BIOSAFETY COMMITTEE

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IV. Audit by the Dept of Audits of IBC practices

Interviews appear to be finished and also the on site visits a report from the auditors is expected soon.

V. Discussion of Draft of animal housing policy

Peter thanked the committee for the comments and discussion and will use them to prepare a revised draft

VI. Survey results of Big 10 IBC's

An interesting look at the work loads of IBC's at other institutions.

VII. New business

It is possible to get room 120 (the large room) if we can change the meeting time to 1:30-3:30.

Members agreed to change the meeting time to 1:30 starting in January.

IBC - from 10/10/05 - 11/09/05**11 projects found**

Project #	P.I.	Project Type	Date	Approved	Summary
<u>894</u>	<u>Argenta, Peter</u>	rDNA	10-OCT-05	31-OCT-05 met cond for app	<u>Efficacy of P125A modified endostatin in murine debulking model of ovarian cancer</u>
<u>895</u>	<u>Low, Walter</u>	rDNA	17-OCT-05	BSO R	<u>Stem Cells and Ischemic Brain Injury</u>
<u>896</u>	<u>Seybold, Virginia</u>	BioTox	17-OCT-05	BSO R	<u>(1) Cannabinoid Modulation of Hyperalgesia (2) Peptidergic Neurotransmission in the spinal cord</u>
<u>897</u>	<u>Bianco, Richard</u>	InfAgent	19-OCT-05	BSO R	<u>Elucidating the Impact of the ON-Q Pain Management System</u>
<u>898</u>	<u>Farassati,</u>	rDNA	25-	BSO R	<u>Production of replication</u>

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	<u>Faris</u>		OCT-05		<u>Incompetent lentiviral system for delivery of DNA/RNA</u>
<u>899</u>	<u>Ji, Yinduo</u>	rDNA	25-OCT-05	BSO R	<u>P1-Identification Of Essential Genes for Mastitis from Bovine Staphylococcus aureus; P2-Identificati...</u>
<u>900</u>	<u>Westendorf, Jennifer</u>	rDNA	31-OCT-05	BSO R	<u>Runx2 Transcriptional Control by Cell Signaling, SUMO-Modification of Runx2 (new)</u>
<u>901</u>	<u>Gregerson, Dale</u>	BioTox	31-OCT-05	FULL REV	<u>#1. Significance of immunological sequestration in the eye; #2. Local retinal antigen presentation; ...</u>
<u>902</u>	<u>Lohr, Jamie</u>	rDNA	02-NOV-05	BSO R	<u>The Role of Cardiac Specific Neural Crest Genes in Heart Development; PINCH-1 Regulation of Neural C...</u>
<u>903</u>	<u>Dykstra, Dennis</u>	BioTox	08-NOV-05	BSO R	<u>A Phase III Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safe...</u>
<u>904</u>	<u>Low, Walter</u>	rDNA	08-NOV-05	FULL REV	<u>The role of endogenous and exogenous stem cells in cerebral ischemia</u>

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

MINUTES **December 12th 2005** **1-3 pm** **Rm. 126 Boynton HS**

Member Roster

Peter Southern (Chair)	James Lauer (BSO)	Claire Kari (NVM staff)
David Brown	Gary Muehlbauer	Carol Siegel (NVM,IRB)
Ann Fitzpatrick	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet (V)	Michael Sadowsky	Leslie Pitt-Schneider (NVM)
Roland Gunther (V)	Mary Anne Sullivan (C)	
Christine Hendrickson	Michael Verneris	
John Hunt (C)	Chester Whitley	

Members absent John Hunt, Cynthia Gillet, Michael Verneris

Quorum (8) 11 members present

Invited guest(s)

Dr. Ji was invited to attend but declined.

Dr. Vince: Jay Bronwell attended in his stead

I. Minutes of the Nov 14, 2005 meeting for ratification

Ratified

Abstentions 0

Nays 0

Yeas 11

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

II. IBC – proposals for review from Nov. 12th -Dec. 8th

Please check over the list for any conflict of interest before the discussion begins

Full review

Ji vote abstentions 0 yeas 11 nays 0

Ask about homogenization procedure and the BSO will evaluate answer and decide if the proposal may be approved.

Vince vote to approve abstentions 0 yeas 11 nays 0

Noreddin vote abstentions 0 yeas 11 nays 0

Ask for an explicit description of the work, how long will the project continue, is the reactor in the biosafety cabinet, provide an experimental plan, provide clarification of his reactor management, how will he prevent selecting for resistant organisms, how much pressure does the reactor operate at, does he need secondary reinforcement of the biosafety cabinet, has he worked with this bioreactor before? His answers will be circulated to the committee by email and the decision will be made then to approve or return the proposal to a meeting for more discussion.

See complete list of proposals on the last page

Block approval abstentions 0 yeas 11 nays 0

Dr. Ohlfest will be asked to identify the lenti vector he is using and provide a hazard assessment of the genes he is moving, his response will be circulated by email and the decision to approve as written or not made then.

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

III. Mary Anne's letter to Dr. Mulcahy commenting on open lab formats

Is there any new information?

No reply has been made to either the first or second letter, committee members were asked to develop questions and identify issues for a communication effort

IV. Audit by the Dept of Audits of IBC practices

The committee was informed that a response from the auditors will probably be available in January.

V. Discussion of Draft of animal housing policy

VII. New business

Change of meeting time for next year: 1:30-3:30. room 120

IBC - from 11/01/05 - 12/08/05

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Project #	P.I.	Project Type	Date of sub	Approved	Summary
897	Argenta	IA		approved	Change of PI from Bianco to Argenta, no changes to protocol
899	Ji REVISED	rDNA		approved after clarification of homogeniz	Answered: homogen done in BSC

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<u>904</u>	<u>Low, Walter</u>	rDNA	08-NOV-05	Still waiting for reply to IBC	<u>The role of endogenous and exogenous stem cells in cerebral ischemia</u>
<u>905</u>	<u>Koepp, Deanna</u>	rDNA	21-NOV-05	approved	<u>SCF Ubiquitin Ligases and Cell Cycle Control Regulation of DNA Replication by an F-box protein</u>
<u>907</u>	<u>Mueller, Joachim</u>	rDNA	21-NOV-05	approved	<u>Fluorescence Fluctuation Spectroscopy in cells</u>
<u>908</u>	<u>Li, Shunan</u>	rDNA	21-NOV-05	approved	<u>Translational control of breast cancer aenesis</u>
<u>909</u>	<u>Kaufman, Dan</u>	rDNA	30-NOV-05	approved	<u>1) Therapeutic Applications of embryonic stem cells, 2) Functional Effects of Runx1 and Runx1-MTG8 E...</u>
<u>910</u>	<u>Ohlfest, John</u>	rDNA	02-DEC-05	Clarified vector and appr	<u>Gene transfer to the CNS for treatment of Parkinson's Disease</u>
<u>912</u>	<u>Vince, Robert</u>	InfAgent	02-DEC-05	approved	<u>Antiviral Chemotherapeutic Agents</u>
<u>913</u>	<u>Noredidin, Avman</u>	InfAgent	02-DEC-05	FULL REV More quest. to be answered before appro	<u>Assessment of Moxifloxacin ability to eradicate and prevent development of Streptococcus pneumoniae ...</u>
<u>914</u>	<u>Samac, Deborah</u>	rDNA	02-DEC-05	approved	<u>Cloning and characterization of genes in a model plant to improve resistance to major pathogens of a...</u>
<u>915</u>	<u>Hackett, Perry</u>	rDNA	05-DEC-05	approved	<u>Sleeping Beauty-Mediated Gene Therapy for Hemophilia</u>
<u>916</u>	<u>Bitterman, Peter</u>	rDNA	05-DEC-05	approved	<u>Translational Control of Fibroblast Viability</u>

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<u>917</u>	<u>Chen,</u> <u>Gang</u>	BioTox	05- DEC- 05	approved	<u>Spreading Acidification and Depression in the Cerebellum</u>
<u>918</u>	<u>Gupta,</u> <u>Sandeep</u>	rDNA	07- DEC- 05	approved	' <u>Cellular Mechanisms of Renal Regeneration:A Transgenic Approach</u> '

INSTITUTIONAL BIO SAFETY COMMITTEE

PREVENT PREPARE PROTECT

MINUTES January 9, 2006 1:30-3:30 pm Rm. W120 Boynton HS

Member Roster

<u>Peter Southern (Chair)</u>	James Lauer (BSO)	Claire Kari (NVM staff)
David Brown	<u>Gary Muehlbauer</u>	<u>Carol Siegel (NVM IRB)</u>
<u>Ann Fitzpatrick</u>	Carol Risdal	Melissa Nellis (NVM)
Cynthia Gillet (V)	Michael Sadowsky	Leslie Pitt-Schneider (NVM)
<u>Roland Gunther (V)</u>	Mary Anne Sullivan (C)	
Christine Hendrickson	Michael Verneris	
<u>John Hunt (C)</u>	Chester Whitley	

A highlighted name denotes a member unable to attend the meeting

Members absent

Quorum (8) nine members were present

Invited guest(s)

Kristin Hogquist 2 pm

I. Minutes of the Dec. 12, 2005, 2005 meeting for ratification

Ratified

Abstentions 1

Nays 0

Yeas 7

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

II. IBC – proposals for review from Dec. 8th - Jan. 5th

Please check over the list for any conflict of interest before the discussion begins

Full review

920 Kristin Hogquist 2 pm

vote: approved

yeas 9, nays 0, abstentions 0

926 Haase (renewal not invited)

vote: approved

yeas 9, nays 0, abstentions 0

913 Noreddin (Duluth review of supplemental mat.)

Instruct Dr. Noreddin to change information for emergency responses to Duluth specific information and remove Mpls. campus information

vote: approved

yeas 8, nays 0, abstentions 0

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See complete list of proposals for consideration on the last page

Block Approval vote: approved

Yeas 9, nays 0, abstentions 0

Exceptions or conditional approval: none

III. Mary Anne's letter to Dr. Mulcahy commenting on open lab formats

Dr. Mulcahy has responded:

Mary Anne:

Dick Bianco reminded me that I still owed you a response to your queries regarding and open lab designs. I apologize again for the lengthy delay in responding. You raise very important questions and issues, the nature of which precluded quick responses which often made it difficult to find the opportunity to prepare a thoughtful response.

In reviewing your questions again I recognized that I am not the right person to offer direct or ultimate responses to the specific issues you raised. I had intended to investigate your scenarios myself to try to find answers, another factor that contributed to a delay in responding. The fact that I would have to do a lot of leg work to respond directly to your questions only served to confirm that I am not the best person to address these issues as a matter of policy. I rely, as do my counterparts at other universities, on the advice and direction of those professionals who are charged with dealing with biosafety issues to advise me when genuine laboratory safety issues exists and to identify appropriate approaches to rectify them. The IBC, BSO and EHS need to consider these issues and the particulars at the University of Minnesota and come forward with a set of guidelines and recommendations that they believe are necessary to comply with regulations and provide adequate protection for investigators. When this concern was first raised and the all standard as an approach was suggested as a possible solution, no one (save yourself) challenged the descision from either a

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regulatory or safety perspective. I interpreted this as an indication that such an approach was acceptable and, considering its practicality, a satisfactory remedy. If that is not the case then the matter should be reconsidered.

Therefore, by copying them on this e-mail response I am referring this matter to Craig Moody, Peter Southern and Dick Bianco instructing them that I want a written assessment of the situation as it exists at the University of Minnesota and a set of written recommendations from the IBC for dealing with the open lab scenario. To limit further delay in resolving this issue, the report will be due by March 1, 2006. Open laboratory formats are the grwoing trend in laboratory design so this particular issue cannot be unique at Minnesota. How is this situation handled elsewhere? As part of the report I would like to see a discussion of approaches employed elsewhere to address this issue. There is an excellent

list_serve of biosafety officers at universities across the country which can serve as a rich resource for this and other types of laboratory safety issues. If the UM IBC is not already plugged into that resource I will get a contact so that such a linkage can be established.

Thanks again for raising your concerns about this situation and for asking excellent questions about the adequacy of the current situation. I confess I do not know the best answer, but will seek advice from those that have the requisite skill set to get answers and to then propose appropriate policy. Thanks, too, for your incredible patience.

Tim

A committee has been formed to respond to Dr. Mulcahy and Dr. Mulcahy has been sent copies of the letters requesting attention to space issues.

IV. Audit by the Dept of Audits of IBC practices

No new information

V. Discussion of Draft of animal housing policy

Animal housing issues were discussed in conjunction with the Hogquist visit.

VI. John Hunt has notified the IBC of his intent to resign as soon as a replacement is found.

Project #	P.I.	Project Type	Date	Status	Summary
913	Noredin, Aymen	InAgent	DEC-02-05	Approv.	Assessment of Moxifloxacin ability to eradicate and prevent development of Streptococcus pneumoniae ...
919	Hosquist, Kristin	BioTox	DEC-19-05	Approv.	Peptide Induction of Positive Selection
921	Chen, Xiaoli	rDNA	DEC-19-05	Approv.	Mechanism of adipose tissue Inflammation-mediated systemic insulin resistance
922	Berman, Judith	rDNA	DEC-20-05	Approv.	Genome Integrity in Candida albicans
923	Bitterman, Peter	rDNA	DEC-21-05	Approv.	Translational Control of Fibroblast Viability
924	Clarke, Duncan	rDNA	DEC-29-05	Approv.	The yeast S-phase Checkpoint

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IBC - from 12/01/05 - 02/01/06

VIII. The calendar for 2006 is available on the IBC member's only page

VII. New business

Change of meeting time for next year: 1:30-3:30. Room 120

Members expressed their gratitude for his service and that he will be missed. The coordinator is making every effort to find a replacement before the next meeting.

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<u>925</u>	<u>Hogquist, Kristin</u>	rDNA	02-JAN-06	Approv.	<u>Receptor Editing in developing T cells</u>
<u>926</u>	<u>Haase, Ashley</u>	InfAgent	03-JAN-06	Approv.	<u>Functional Genomic Analysis of HIV-1 Infection in LTs</u>
<u>927</u>	<u>Campbell, Colin</u>	rDNA	05-JAN-06	Approv.	<u>Rad50-dependent end joining in human somatic cells (NIH) The role of Nibrin in DNA end-joining and c...</u>
928	Chun Wang	rDNA	06jan06	Approv.	<u>Biomimetic Engineering of Responsive Biomaterials</u>

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MINUTES February 13, 2006 1:30-3:30 pm Open Meeting Rm. W120 Boynton HS

Member Roster

<u>Peter Southern (Chair)</u>	Gary Muehlbauer	Claire Kari (NVM staff)
David Brown	Carol Risdal	Carol Siegel (NVM,IRB)
Ann Fitzpatrick	<u>Michael Sadowsky (co-chair)</u>	Melissa Nellis (NVM)
Cynthia Gillet (V)	Mary Anne Sullivan (C)	Leslie Pitt-Schneider (NVM)
Roland Gunther (V)	<u>Michael Verneris</u>	
<u>Christine Hendrickson</u>	<u>Amy Verhoeven (C)</u>	
James Lauer (BSO)	<u>Chester Whitley</u>	

A highlighted name denotes a member unable to attend the meeting

James Lauer was acting chair for the meeting

Members absent

Quorum (8)

Invited guest(s)

Walter Low's group 2:30

4 visited the IBC: Walter Low, Terry Burns, Scott McIvor, Nicholas S.

I. Minutes of the Jan.9 2005, meeting for ratification

Ratified

Abstentions (8)

Nays (0)

Yeas (8)

II. ImageNow access request forms

INSTITUTIONAL BIOSAFETY COMMITTEE

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Members filled out data security forms to gain required permissions to use WebNow the new IBC protocol management and archiving system. Training will be provided at a meeting soon.

III. IBC – proposals for review from Jan. 9th to Feb. 9th

Please check over the list for any conflict of interest before the discussion begins

Full review

904 Walter Low 2:30pm

vote: yeas, nays, abstentions

Discussion is tabled until the next meeting of the IBC

Dr. Low wrote in a communication that he had consulted with experts on issue of using modified lenti vectors at . The committee then asked if he would be willing to bring them to a meeting. He agreed and brought several experts to the meeting. They presented a panel discussion explaining why the committee was being asked to consider approving work with modified lenti viral vectors at BL1. The committee listened and asked questions and after deliberating decided to ask Dr. Low to update his proposal of Dec. 9th to reflect the changes he is asking for and the IBC members will continue the review of his proposal at the next meeting of the IBC.

Specifically: explain in depth why this vector is safe to use at

Write SOP for the response to accidental injection (needle stick) exposure

Distinguish and explain injection procedures: those on steriotactic apparatus and those that are not

948 Sharma

vote: yeas (8), nays (0), abstentions (0)

Dr. Sharma's proposal is approved if three conditions are met:

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He will provide the IBC with the name of the person or person's authorized to receive the virus in the Lab. The lab must agree to restrict delivery to designated personnel

He will provide the IBC with procedures for decontaminating the rotor and opening it in the biosafety cabinet after a 15 min. wait.

An eyewash will be installed and operational before any work with the virus is done. Dr. Sharma will inform the IBC when it is operational.

#949 Bianco

vote: yeas (8), nays (0), abstentions (0)

It is the decision of the committee to approve the proposal with the following stipulations: The IBC and RAR will be provided with an antibiotic susceptibility profile for each infectious agent and SOP's describing what will be done if a bandage comes off a wound. Upon receipt of the information Roland (RAR) and Jim (BSO) will decide if it can be approved as written. If the material the Bianco group proposes to use is resistant to multiple antibiotics and poses more risk than stated in the proposal Jim and Roland will not approve it and it will be returned to the committee..

Ann Fitzpatrick is Dick Bianco's supervisee and the procedure for possible conflict of interest recommended by the General Counsel, Keith Dunder, was followed. The procedure is as follows: "There are two basic approaches ...to situations of possible conflict of interest. The first is to require panel members to recuse themselves whenever there is any sort of connection with an issue or decision being put before the board. The second is to require disclosure of any possible conflict, but to not require recusal unless a board member or the PI requests it. I lean toward the second approach, as long as it is used conservatively, that is, that after disclosure, which the minutes should reflect. The panel member recuses himself if there is any discomfort about participation. And there should be discomfort if there is something like a direct supervisory relationship involved, or if the panel member has some significant stake in the research."

#931 Fatemi (IA, therefore exempt from NIH guidelines, was reviewed by email because of funding issues)

Approval letter has the following stipulation: No culture of virus is approved. Dr. Sharma will seek separate IBC approval to his component of this proposal.

vote: yeas (9), nays (0), abstentions (5)

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Since the vote on the approval more facility problems were discovered and Dr. Fatemi has been assigned another biosafety cabinet in that has been certified. This required a change to protocols for the work done in and the changes were reviewed and approved by the committee with a vote of

Yeas (8), nays (0), abstentions (0) with the stipulation that the first time the experiment is done Dr. Fatemi's researcher will contact the Biosafety group (Melissa Nellis 6-5892 or Darlene Charboneau 4-5479) and go through the protocol with a Biological Safety staff person present to review and observe the new procedures. If the Biosafety cabinet that is described in the proposal can be certified (at present it has failed certification) and is used it is not necessary to have an observer from the Biosafety group.

See complete list of proposals for consideration on the last page

Block Approval vote:

Yeas (8), nays (0), abstentions (0)

Exceptions or conditional approval:

All were approved as submitted. Carol Risdal requests a list of evaluation criteria for assigning protocols to Full Review or BSOR and the Biosafety group will develop a formal procedure to replace the informal procedure

IV. Mary Anne's letter to Dr. Mulcahy commenting on open lab formats.

Craig Moody, EHS director, has formed a committee to reply to Dr. Mulcahy's request for more information.

V. Audit by the Dept of Audits of IBC practices

The dept. of audits has had no further communication with the IBC.

VI. Discussion of Draft of animal housing policy

INSTITUTIONAL BIOSAFETY COMMITTEE

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VII. Please welcome Amy Verhoeven, Nicole Reynolds, and Adrienne Schucker. Nicole is considering joining the IBC as a community member. We hope she will be able to join our committee. Amy and Adrienne have agreed to serve as community members on the IBC.

As soon as the IBC office receives their CV's a request to appoint them will be sent to the VP for Research. The VP for Research will send them a formal letter of appointment.

VIII. John Hunt sends his regards to committee members and his regrets that because of scheduling conflicts at Health Partners he is no longer able to serve on the IBC.

IX. New business

Time and place of meeting: 1:30-3:30. Room W120
4 laptops for the IBC's use have been ordered

X. The calendar for 2006 is available on the IBC member's only page

List of IBC Proposals for review

IBC - from 01/10/06 - 02/08/06

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22 projects found

Project #	P.I.	Project Type	Date	Status	Summary
904	Low	rDNA	9DEC06	Full Review Tabled until Mar 13	The role of endogenous and exogenous stem cells in cerebral ischemia
<u>929</u>	<u>Borjesson, Bori</u>	InfAgent	11-JAN-06	App	<u>Granulocytic Ehrlichiosis: Cell-Pathogen interactions</u>
<u>930</u>	<u>McIvor, Scott R</u>	rDNA	11-JAN-06	App	<u>Transposon-Mediated Gene Therapy for Colorectal Cancer</u>

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<u>931</u>	<u>Fatemi, S.Hosseini</u>	InfAgent	11-JAN-06	App. Addendum approved with stipulations	<u>Prenatal virally induced brain disorder in mouse</u>
640	Schendel update of proj			App	BPTI (Biotechnology Processing Intitute)
<u>933</u>	<u>Kapur, Vivek</u>	InfAgent	12-JAN-06	App	<u>Study of pathoaenesis mechanisms usina Acanthamoeba polyphaaa as host system for Lawsonia intracell...</u>
<u>934</u>	<u>Nakato, Hiroshi</u>	rDNA	17-JAN-06	App	<u>Molecular mechanisms of morphoaen aradiant formation</u>
<u>935</u>	<u>McSorley, Stephen J</u>	BioTox	23-JAN-06	App	<u>CD4 T cell response to Salmonella: Immune response to bacterial flagellins; In vivo tracking of anti...</u>
<u>938</u>	<u>Zeng, van</u>	rDNA	25-JAN-06	App	<u>Regulation of microRNA biogenesis and function</u>
<u>939</u>	<u>Martemvanov, Kirill</u>	rDNA	27-JAN-06	App	<u>Expression of RGS Proteins in the Brain</u>
<u>940</u>	<u>Jameson, Stephen</u>	rDNA	30-JAN-06	App	<u>T cell Homeostatsis</u>
<u>941</u>	<u>Kelekar, Ameeta</u>	rDNA	30-JAN-06	App	<u>Using lentiviral vectors to eliminate the expression of proteins in leukemia cell lines</u>
<u>942</u>	<u>Shima, Naoko</u>	rDNA	30-JAN-06	App	<u>Role of the MCM family in preserving genomic stability and preventing cancer</u>

944	Polunovsky, Vitaly	rdNA	01-FEB-06	App	Disruption of Breast Cancer Chemoresistance by the Translational Antagonist 4E-BP1: A Bitransgenic M...
945	Kelekar, Ameeta	rdNA	01-FEB-06	App	Identifying Survival Signals from Damaged Mitochondria in Breast Cancer Cells
946	Lin, Jizhen	InfAgent	01-FEB-06	App	Identify and develop otitis media models
947	Noireaux, Vincent	rdNA	06-FEB-06	App	Artificial based on in vitro gene expression
948	Sharma, Jagdev	InfAgent	06-FEB-06	App with stipulations	Prenatal virally induced brain disorder in mouse
949	Bianco, Richard	InfAgent	06-FEB-06	App dependent upon supp. info	Photodynamic Therapy (PDT) Wound Bandage
950	Ji, Yinduo	BioTox	07-FEB-06	App	Mechanisms of anthrax toxin in inducing cell death
951	Segal, Yoav	rdNA	07-FEB-06	App	Genetics of Familial Kidney Diseases, Molecular Genetics of Medullary Cystic Kidney Disease
952	Largaespada	rdNA	08-FEB-06	App	"Characterization of a Regulated Model of NRAS(V12)-Driven Myeloid Leukemia in Mice" "Mouse Models of Myeloid Leukemia Dev"

INSTITUTIONAL BIOETHICS COMMITTEE
 PREPARED BY: PROJECT

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

Minutes March 13, 2006 1:30-3:30 pm Rm. W120 Boynton HS

Member Roster

Peter Southern (Chair)	Gary Muehlbauer	<u>Amy Verhoeven (C)</u>
David Brown	<u>Carol Risdal</u>	<u>Chester Whitley</u>
Ann Fitzpatrick	Michael Sadowsky (co-chair)	Xiaohong Chen (NVM staff)
<u>Cynthia Gillet (V)</u>	<u>Adrienne Schucker (C)</u>	<u>Claire Kari (NVM staff)</u>
Roland Gunther (V)	Mary Anne Sullivan (C)*	<u>Carol Siegel (NVM; IRB)</u>
Christine Hendrickson	Michael Verneris	Melissa Nellis (NVM staff)
<u>James Lauer (BSO)</u>		<u>Leslie Pitt-Schneider (NVM)</u>

* via phone

A highlighted name denotes a member who is unable to attend the meeting

Cynthia Gillet (V)
James Lauer (BSO)
Carol Risdal
Adrienne Schucker (C)
Amy Verhoeven (C)
Chester Whitley
M staff)
Carol Siegel
Leslie Pitt-Schneider

nine members were present

Invited guest(s)

Marilyn Carroll 2pm

Dr. Carroll didn't attend the IBC meeting because of the snow storm.

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

I. Minutes of the Feb.13, 2006, meeting for ratification

Ratified

Abstentions (0)

Nays (0)

Yeas (9)

II. ImageNow access request forms and progress report

Michael Verneris filled out data security forms to gain required permissions to use WebNow the new IBC protocol management and archiving system. Data security form has been faxed to OIT data security.

III. IBC – proposals for review from Feb. 9th to Mar. 9th

#904 Low Update:

Dr. Low was asked to provide a revised protocol describing the biosafety level requested and rationale.

Specifically: explain in depth why this vector is safe to use at

Write SOP for the response to accidental injection (needle stick) exposure

Distinguish and explain injection procedures: those on stereotactic apparatus and those that are not

Dr. Low submitted a revised protocol. This protocol indicates conditions for stereotaxic injection of lentiviral constructs, provides safety features of lentivirus to be used, includes accident SOP for needle stick, and explains that lentivirus will be injected only into the brain using stereotaxic apparatus.

Dr. Low's protocol is approved.

Vote: yeah (9) nay (0) abstentions (0)

Conditions for approval:

INSTITUTIONAL BIOSAFETY COMMITTEE

PENDING PREPARED PROPOSED

#931 Fatemi Update:

"Since the vote on the approval more facility problems were discovered and Dr. Fatemi has been assigned another biosafety cabinet in that has been certified. This required a change to protocols for the work done in and the changes were reviewed and approved by the committee with a vote of

Yeas (8), nays (0), abstentions (0) with the stipulation that the first time the experiment is done Dr. Fatemi's researcher will contact the Biosafety group (Melissa Nellis 6-5892 or Darlene Charboneau 4-5479) and go through the protocol with a Biological Safety staff person present to review and observe the new procedures. If the Biosafety cabinet that is described in the proposal can be certified (at present it has failed certification) and is used it is not necessary to have an observer from the Biosafety group."

We have received the stipulation and are willing to comply.

Sincerely,

Teri Reutiman

626-1452

Claire Kari wrote:

Dear Dr. Fatemi and Teri,

The IBC has reviewed your amendment to change to another procedure room in with a certified Biosafety Cabinet. Your request is approved upon the following condition / stipulation: the first time the experiment is done Dr. Fatemi's researcher will schedule the time with the Biosafety group (Melissa Nellis 6-5892 or Darlene Charboneau 4-5479) and go through the protocol with a Biological Safety staff person present to review and observe the new procedures. If the Biosafety cabinet that is described in the proposal can be certified (at present it has failed certification) and is used it is not necessary to have an observer from the Biosafety group./

Please let me know that you have received this stipulation and if you are willing to comply.

Regards,

Claire

Claire,

RAR RESPONSE:

fyi - the biosafety cabinet in Fatemi's influenza mouse study.

has been recertified and is now available for Dr.

Cyd

Fatemi group met conditions set by the IBC and their addendum was approved

#949 Bianco Update:

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVIEW PREPARE PROTECT

"It is the decision of the committee to approve the proposal with the following stipulations: The IBC and RAR will be provided with an antibiotic susceptibility profile for each infectious agent and SOP's describing what will be done if a bandage comes off a wound. Upon receipt of the information Roland (RAR) and Jim (BSO) will decide if it can be approved as written. If the material the Bianco group proposes to use is resistant to multiple antibiotics and poses more risk than stated in the proposal Jim and Roland will not approve it and it will be returned to the committee.."

Jim and Roland each reviewed all the responses and agree it is approvable.

In accordance with the IBC's instructions it was approved and all documents were added to the Bianco #949 file.

#961 Carroll Towards a Gene Therapy for Cocaine Addiction

Ask to provide complete scientific summary so that committee can understand the project, submit a modified SOP for needle stick so it can be approved by the committee, complete Preventing Employee Exposure to Bloodborne and Other Pathogens training. The committee request that Jim (BSO) and Roland (RAR) visit the facilities and review procedures with Dr. Carroll and determine whether Dr. Carroll should have a dedicated room for the experiment or if other animals can be housed in that room. Her response will be reviewed by the committee on the next meeting.

Yeas (), nays (), abstentions ()

Exceptions or conditional approval:

948 Sharma update:

Mahesh Khatri in 's lab sent an email to IBC. In this email he indicates that Teri Reutiman in lab is authorized to receive the virus. He also provides safety procedures for centrifuge.

Dr. Sharma's protocol is approved.

Yeas (9), nays (0), abstentions (0)

INSTITUTIONAL BIOSAFETY COMMITTEE

PREVENT PREPARE PROTECT

#961 Loh Basic Research Center on Molecular and Cell Biology of Drug Abuse

Ask to clarify LD₅₀ of the toxins by the route, provide more information about the antidote in question 12, provide detailed procedures regarding how animals will be injected and handled (e.g. restrained or sedation), clarify how many rabbits and mice will be used in this project, how many injections each animal will receive, provide accident SOP for needle stick. His responses will be reviewed by the committee on the next meeting.

Yeas (), nays (), abstentions ()

Exceptions or conditional approval:

#964 Weinig Molecular Evolutionary Genetics of Crop and Weed Responses to Crowding

Dr. Weinig will be asked to provide copies of relevant documents from APHIS and MN Department of Agriculture giving approval for the release. Approved pending receipt of documents by BSO.

Protocols Removed from the BSORA List for Individual Review

#955 Huo Leukocyte Homing Mechanisms

Dr. Huo will be asked to provide a description of each gene function is, identify where the blood is obtained, whether the employees are offered Hepatitis B vaccine and completed Preventing Employee Exposure to Bloodborne and Other Pathogens training. The committee has requested that Jim (BSO) review the responses and if satisfies the committee's concerns the proposal will be approved.

#960 Wang Polymers for DNA Vaccine Delivery

Dr. Wang will be asked to provide procedures regarding how potential aerosols generated by polymers can be contained and prevented. Chemical Hygiene Officer must approve chemical safety plan before his proposal is approved by IBC.

See complete list of proposals for consideration on the last page

Block Approval vote:

INSTITUTIONAL BIOSAFETY COMMITTEE

PRESENT PREPARED PROTECT

Yeas (9), nays (0), abstentions (0)

IV. Mary Anne's letter to Dr. Mulcahy commenting on open lab formats.

Craig Moody, EHS director, has formed a committee to reply to Dr. Mulcahy's request for more information and the reply is due date has been extended to Apr. 1

V. Audit by the Dept of Audits of IBC practices

The dept. of audits gave a draft of the audit to Peter, Jim, Craig, and Claire.

VI. Mike Sadowsky is resigning from the IBC effective Mar.13th.

He has accepted an appointment to be one of the Directors of the Microbial and Plant Genomics Institute. I am sure I can speak for the IBC membership and say we will miss his expertise, enthusiasm, and commitment very much.

VII. Carol Risdal requests a list of evaluation criteria for assigning protocols to Full Review or BSOR and the Biosafety group will develop a formal procedure to replace the informal procedure

Jim has been working on this and it will be available soon

IX. New business

Time and place of meeting: 1:30-3:30. Room W120
3 new laptops for the IBC's are available

X. The calendar for 2006 is available on the IBC web page and member's only page

IBC proposals for review from 02/09/06 - 03/08/06

Project #	P.I.	Project Type	Date	Status	Summary
451	Jameson	addendum	2/23/06	App	Protocol change involving infected mice
346	Jameson	addendum	2/23/06	App	Protocol change involving infected mice
620	Zhou	addendum	2/28/06	App	Add transposon piggyBac
904	Low, Walter	rDNA	Nov 05	App	The role of endogenous and exogenous stem cells in cerebral ischemia
931	Fatemi	IA		Approved	Addendum: RAR facilities
949	Bianco	IA	2/6/06	Approved	Photodynamic Therapy Wound Bandage
953	Largaspada, David A	rDNA	23-FEB-06	Submitted not ready for review	'Sleeping Beauty for uncovering cancer genes in mice' Transposon-based somatic mutagenesis/prostat...
954	Mansky, Louis	rDNA	23-FEB-06	Submitted not ready for review	Mechanisms of adenovirus DNA packaging
955	Huo, Yunging	rDNA	27-FEB-06	Still waiting for reply to IBC	Leukocyte homing mechanisms
956	Loh, Horace H	BioTox	27-FEB-06	Full Rev More questions to be answered before approval	Basic Research Center on Molecular and Cell Biology of Drug Abuse
957	Kazlauskas, Romas	rDNA	27-FEB-06	App	Site-Directed Mutagenesis to Improve the Enantioselectivity and/or Reactivity of Candida antarctica ...
958	Murphy, Sharon	rDNA	28-FEB-06	App	Nicotine Inactivation of P450 2A enzymes;

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					<u>Cytochrome P450 in Nicotine Metabolism</u>
<u>959</u>	<u>De Larco, Joseph</u>	rDNA	01- MAR- 06	App	<u>Does methylation of two 5' CpG sites in the IL-8 gene contribute to the ectopic release of IL-8?</u>
<u>960</u>	<u>Wang, Chun</u>	rDNA	06- MAR- 06	Full Rev Need chemical safety plan is approved before approval	<u>Polymers for DNA vaccine delivery</u>
<u>961</u>	<u>Carroll, Marilyn</u>	rDNA	07- MAR- 06	Full Rev More questions need to be answered before approval	<u>Towards a Gene Therapy for Cocaine Addiction</u>
<u>962</u>	<u>Gupta, Pankaj</u>	rDNA	08- MAR- 06	App	<u>Correction of Hurler syndrome by multipotent stem cells</u>
963	Frank Burton	rDNA	3/08/06	App	Restoring a Ubiquitously Down Regulated Breast Oncogene Repressor
<u>964</u>	<u>Weinig, Cynthia</u>	rDNA	08- MAR- 06	Provide USDA approval for the release before app	<u>Molecular evolutionary genetics of crop and weed responses to crowding</u>

Minutes were prepared by Xiaohong Chen