



Office of the Custodian of Records

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UNIVERSITY OF MISSOURI

April 28, 2006

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

Dear Mr. Hammond:

Your letter dated March 15, 2006 and addressed to Arthur Karr, Jr. at the University of Missouri-Columbia was forwarded to me in my capacity as Custodian of Records for the University of Missouri. In that letter you requested minutes of all meetings of the University of Missouri-Columbia Institutional Biosafety Committee since May 1, 2003.

In response to your request and in accordance with NIH Guidelines, I have enclosed copies of minutes provided by that committee.

Please direct any further questions to my attention.

Sincerely,

David R. Russell
Custodian of Records

COR #800

COLUMBIA KANSAS CITY ROLLA ST. LOUIS

INSTITUTIONAL BIOSAFETY COMMITTEE MEETING
Research Park Development Building, Room 12
January 17, 2006 3:30 PM

Members Present

Brenda Beerntsen, Vice Chair
Lon Dixon
Steve Hincey
Arthur Karr, Jr., Chairman
Katharine Mayne
Roy Parsons
Michael Rovetto
Charles Sanders

Guests Present

Beth Asbury, CF Project Mgmt
Peter Ashbrook
William Dale
Michele Kennett, IRB
Roger Riddlemoser
Doug Spellman, CF Project Mgmt
Betty Wilson, IRB

Members Absent

Frank Schmidt
Chris Smith
Richard Tsika

Dr. Karr called the meeting to order at 3:30 PM with the required quorum in attendance.

Review of 11/15/05 Meeting Minutes

Karr asked for a motion to approve the November 15, 2005 IBC minutes. Mayne moved for approval of the minutes, Hincey seconded, and the motion was approved unanimously.

Ashbrook informed members that per their request during the 11/15/05 IBC meeting, he spoke with BU #2084 concerning his approved protocol #05-33. Ashbrook contacted the researcher to assure the researcher understands this committee has approved the researcher's work with a non virulent strain only. Ashbrook assured members that BU #2084 understands that this committee has not approved any work with a virulent strain.

Review of Approved Protocols

Review of Protocols Approved Since 11/15/05 Meeting

The committee packet included a listing of all protocols submitted for this committee's review between 11/15/05 and 1/16/06. The listing includes:

- 2 follow-up protocols from the 11/15/05 meeting
 - 7 new protocols reviewed during the time period
- Three protocols required full committee review. All three were initially approved via committee email vote. *The remaining four protocols were approved (tentatively) by the IBC Chairman and Biosafety Professional and now require approval by the full committee.*

BU#1151 05-34 *"Estrogen Receptor Conformation to Predict In Vivo Xenoestrogen Activity" (follow-up previously requested)*
(FOLLOW-UP)

Parsons informed members that per their request during the 11/15/05 IBC meeting, he has verified that the human cell lines for this protocol are level 1 only. Dixon moved for approval, Beerntsen seconded, unanimous approval.

**BU# Applying
(FOLLOW-UP)**

"A Phase II Study of the Efficacy, Safety and Immunogenicity of OncovexGM-CFS in Patients with Stage IIIc and Stage IV Malignant Melanoma" IRB Protocol #1050876

Continue to hold vote for additional information.

Parsons directed attention to additional protocol information provided in today's packet: letter from researcher to IRB Chair dated 1/9/2006 and Patient & Caregiver Instructions for Dressing Changes at Home. Members discussed additional information but continue to have questions:

1. Will patients be sent home when Herpes Virus is still being excreted?
2. This committee is concerned about exposure to other visitors/patients in the guest house. Dixon asked if patients can be kept somewhere other than the guest house. Dr. Karr is specifically concerned about crossover of this virus with the everyday Herpes Virus.
3. Has there been recombination of Herpes in any other patient?

Parsons reported that the NIH Resource Advisory Council (RAC) reviewed the protocol but had no comments and that the University Hospital Infection Control Nurse also reviewed the protocol and had no comments/concerns. IRB staff met with General Counsel and Risk Management and both felt that MU had no recourse to "hold" these patients if they refuse to remain during the time that the Herpes Virus is being excreted. Betty Wilson/IRB representative stated that this study has the potential to accept up to five patients only at this location. Karr recommended that the IBC wait for additional information from the IRB---this group can do email approval if questions are clearly addressed.

BU# 3516 06-06 "*Antiviral Immunoproteome of the Budworm, Heliothis Virescens*"
Dixon moved for approval, Beerntsen seconded, unanimous approval.

BU# Applying 06-03 "Influence of Aging on the Autonomic Nervous System"

Rovetto was primary reviewer for this protocol submission. Parsons stated he would provide blood borne pathogen training for the researcher and lab staff. The researcher is an MU faculty member doing research in a VA laboratory. The BSP was not sure if he would be able to inspect the lab. Sanders questioned who is responsible for the lab---MU or VA? If this committee is asked to approve this protocol, the IBC and MU BSP must have oversight. Dr. Hall suggested that Jerry Parker/VA be invited to the next meeting of this committee. Dr. Hall stated he would review language in the MU/VA contract. Mayne moved for approval with the condition that a memo of understanding exists that the University has access to the lab, Sanders seconded, unanimous approval.

BU# Applying 06-01 "Arginase and Arterial Injury; Arginase and Vascular Remodeling in Diabetes; Carbon Monoxide and Voocular Smooth Muscle Cell Functions; Regulation of Platelet-Endothelial Interactions"

Schmidt was primary reviewer for this protocol submission. Parsons informed members he still needs to inspect the lab and provide training. Sanders moved for approval, with the condition that the laboratory inspection and staff training are completed prior to work beginning in the lab, Dixon seconded, unanimous approval.

BU# Applying 06-04 "*Carbon Monoxide and Endothelial Dysfunction in Diabetes; Regulation of Platelet-Endothelial Interactions*"

Dixon moved for approval, Beerntsen seconded, unanimous approval.

BU#2098 06-02 "Inflammatory Cytokine Networks During Acute West Nile Virus Infection"

Dixon was primary reviewer for this protocol submission. BU#2098 is a new MU researcher and plans to continue work begun by BU#2070. Beerntsen commented that laboratory facilities are

even better than when BU#2070 was approved for this same type of research. Parsons has *additional* training to do with new laboratory staff. Dixon moved for approval, Sanders seconded, and approval was granted. Beerntsen abstained from voting due to a mutual interest in the protocol.

BU#2045 06-05 *"AAV-Mediated Gene Therapy in Canine Muscular Dystrophy"*
This is a protocol continuation. Dixon moved for approval, Beerntsen seconded, unanimous approval.

BU#3121 06-07 *"Production of eGFP Swine"*
Dixon moved for approval, Beerntsen seconded, unanimous approval.

Old Business

Annual Protocol Renewal On-Line (update)

Parsons reported that the 2005 Annual Protocol Renewal On-Line process was completed earlier this month.

NIH & BMBL Guidelines for MU BSL-2 Construction

Presentation by Steve Hency, Beth Asbury, and Doug Spellman/CF Project Management which provided information on the various codes and guidance on laboratory design to address biohazards. The presentation is available in PowerPoint format from either Hency or Parsons. A printout of the PowerPoint screens will be included in the archived packet of this meeting.

IRB #1050876 Protocol Submitted for IBC Review

Discussion by members during Review of Protocols—earlier in this meeting.

New Business

Sanders had previously requested a report of the number of initial and periodic BL2 laboratory inspections completed by the Biosafety Professional during the last year. Riddlemoser reported the totals to committee members. Sanders expressed concern that the number of inspections completed does not appear to meet NIH guidelines. Current NIH guidelines require that all BSL2 laboratories undergo "periodic" inspections. "Periodic" is generally taken to mean annual. Parsons commented that an EHS staff member completes annual inspections of laboratory hoods and an outside vendor is contracted to complete annual biosafety cabinet inspections. Ashbrook explained that the EHS Radiation Safety (RS) group completes laboratory inspections quarterly for Authorized Users and that the EHS EMS Hazardous Materials Services (HMS) group completes laboratory inspections three times per year. Ashbrook has initiated an effort to review how EHS conducts all of these inspections and to try to find ways to deliver these inspections more efficiently—for the benefit of both researchers and EHS.

Dixon made a motion that a letter be addressed to Dr. Jim Coleman, Vice Provost for Research, from the IBC. The letter should inform Dr. Coleman:

- of the NIH periodic inspection requirement for rDNA BSL-2 or higher laboratories and the MU triennial inspection requirement for rDNA BSL-1 laboratories.
- MU EHS is unable to meet these requirements because of staffing limitations.
- MU should provide adequate resources to conduct inspections of rDNA laboratories in

accordance with NIH requirements.
Mayne seconded the motion, unanimous approval.

Open Discussion

None

Next IBC Meeting Dates

- March 21, 2006 3:30PM in Room #12 Research Park Development Building
- May 16, 2006 3:30PM in Room #12 Research Park Development Building

This meeting was adjourned at 5:35PM.

Respectfully submitted,

Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE MEETING
Research Park Development Building, Room 12
November 15, 2005 3:30 PM

Members Present

Brenda Beerntsen, Vice Chair
Lon Dixon
Steve Hencey
Steven Kleiboeker
Katharine Mayne
Roy Parsons
Michael Rovetto
Charles Sanders
Frank Schmidt
Richard Tsika

Members Absent

Arthur Karr, Jr., Chairman
Chris Smith

Others Present

Peter Ashbrook
Michele Kennett, IRB
Jennifer Pratt May
Roger Riddlemoser
Betty Wilson, IRB

Dr. Beerntsen called the meeting to order at 3:30 PM with the required quorum in attendance.

Old Business

NIH & BMBL Guidelines for MU BSL-2 Construction

Riddlemoser reported that a working group continues to meet regularly. The group's focus is to develop guidelines for campus BL2 laboratories. The group plans to make a presentation during the January 2006 IBC meeting. The group is reviewing NIH as well as BMBL guidelines.

New Business

Annual protocol renewal on-line (update)

Riddlemoser reported that a message has been sent to all researchers with active IBC approved protocols. The message informed researchers that they are required to update their protocol information.

Review of 9/20/05 Meeting Minutes

Beerntsen asked for a motion to approve the September 20, 2005 IBC minutes. Sanders moved for approval of the minutes, Dixon seconded, and the motion was approved unanimously.

Review of Approved Protocols

Review of Protocols Approved Since 5/18/05 Meeting

The committee packet included a listing of all protocols submitted for this committee's review between 9/20/05 and 11/14/05. A total of 9 protocols: Six protocols require full committee review—(of the six)—three were initially approved via committee email vote, two were previously mailed to members and are for committee vote today, and one protocol is pending IRB as well as IBC review and for discussion during the meeting today. *The remaining three protocols were approved (tentatively) by the IBC Chairman and Biosafety Professional and now require approval by the full committee.*

- BU#3802** 05-30 *"Defense Peptides to Protect Soybean from Rust"*
Mayne moved for approval, Dixon seconded, unanimous approval.
Parsons reported that this researcher's lab was approved by the USDA
- BU# Applying** 05-31 *"Potential Role of Glycosylation in AIDS Pathogenesis"*
Sanders moved for approval contingent on training of laboratory staff,
Mayne seconded, unanimous approval.
Parsons reported this RU's training is pending completion of this lab. The lab should be ready to go in 6-8 weeks.
- BU#4084** 05-32 *"The Role of Caveolin-2 in Endothelial Cell Function"*
Dixon moved for approval contingent on final inspection and training of laboratory staff, Hencey seconded, unanimous approval
Parsons reported this researcher will be using human cell lines. His lab is on the 5th floor of the Medical Science Building. The researcher's work is funded by the American Heart Association
- BU#2084** 05-33 *"Systematic Mutagenesis of the Francisella Tularensis Surface Proteome and Secretome"*
Mayne moved for approval, Kleiboeker seconded, unanimous approval.
Parsons reported this is a CDC exempt strain and that the researcher is aware he must not have a virulent strain of Francisella Tularensis. Members suggested strains arriving be tested. Ashbrook will meet with the researcher to clarify that he must use an approved strain.
- BU#4076** 05-37 *"AAV Gene Therapy in Canine Model"* (For vote during this meeting)
Rovetto moved for approval, Dixon seconded, unanimous approval.
Schmidt was primary reviewer for this protocol submission. Parsons reported a concentration update from BU#4076. Dixon asked about housing the dogs---hold for 48-72 hours. Injection is directly into the leg muscle.
- BU# Applying** 05-36 *"Tick Transmission of Anaplasmatidae"* (For vote during this meeting)
Dixon moved for approval, Rovetto seconded, unanimous approval.
Dixon was primary reviewer for this protocol submission. Dixon explained protocol and that this researcher brought his research dog with him and the dog is under ACUC housing only protocol. Approval would be pending approval of lab and training of personnel. Dixon is comfortable with the protocol and recommends approval
- BU# Applying** 05-34 *"Estrogen Receptor Conformation to Predict In Vivo Xenoestrogen Activity"*
Hold vote for next meeting---Parsons will request that researcher complete Appendix A-3
- BU#3141** 05-35 *"Generation of Porcine Fibroblasts With Mammary Gland-Specific Transgenes"*
Dixon moved for approval, Schmidt seconded, unanimous approval.
This researcher is working with BU#3121 on a pig project. All transgenic animals are incinerated to keep them out of the food chain
- BU# Applying** *"A Phase II Study of the Efficacy, Safety and Immunogenicity of OncovexGM-CFS in Patients with Stage IIIc and Stage IV Malignant Melanoma"* IRB Protocol #105076
Hold vote for additional information from researcher.

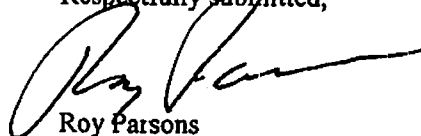
Parsons informed members of preliminary review done by himself and Dr. Tsika. Parsons has conducted Biosafety and Bloodborne Pathogen Training for the researcher and staff. Parsons has conducted site visits of the clinical area, treatment area, and EFCC guest housing. Parsons explained daily plan for patient---it is assumed that viral shedding could occur for up to 72 hours. In order for patient to be released he/she must have three clear tests in a 24 hour period. A caregiver will accompany patient throughout care. Members discussed need for medical ID card for patients. This committee's recommendation must focus on protecting the community and other patients. The IRB's review will focus on the risk to patients participating in the study. A December meeting of this committee may be necessary to review additional information concerning this protocol submission. Steve Hencey will talk with Hospital Engineering Manager/Larry Hall about air flow in the OR suite (treatment area) and EFCC Guest House (housing area)—need negative or neutral pressure (not positive). Additional question---How long will HSV last? IRB meeting scheduled for tomorrow, 11/16/05. Parsons will refer information from the IRB to this committee.

Next IBC Meeting Dates

- January 17, 2006 3:30PM in Room #12 Research Park Development Building
- March 21, 2006 3:30PM in Room #12 Research Park Development Building

This meeting was adjourned at 5:25PM.

Respectfully submitted,



Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE
September 20, 2005 3:30PM
Room #12 Research Park Development Building

Members Present

Brenda Beerntsen, Vice Chair
Arthur Karr, Jr., Chair
Katharine Mayne
Roy Parsons
Michael Rovetto
Charles Sanders
Frank Schmidt
Chris Smith
Richard Tsika

Guests Present

Bill Dale, Ex Officio
Roger Riddlemoser
Jennifer Pratt May

Members Absent

Lon Dixon
Steve Hencey
Steven Kleiboeker

Arthur Karr, Jr., Chair, called the meeting to order at 3:30 p m with the required quorum in attendance.

Review 5/18/05 Meeting Minutes

Karr asked for a motion to approve the May 18, 2005 IBC minutes. Schmidt moved for approval of the minutes, Mayne seconded, and the motion was approved unanimously.

Review of Approved Protocols

Review of Protocols Approved

The committee packet included a listing of all protocols submitted for this committee's review between 5/18/05 and 9/19/05. A total of 13 protocols were reviewed: Two protocols required full committee review. *The remaining eleven protocols required the IBC Chairman and Biosafety Professional's review and approval.*

- BU#3145** 05-17 "*Gene sequencing*"
Schmidt moved for approval, Mayne seconded, unanimous approval.
- BU#3144** 05-18 "*Gene sequencing*"
Schmidt moved for approval, Mayne seconded, unanimous approval.
- BU#3008** 05-19 "*Quantification of atrazine-degrading Pseudomonas SP ADP in soils*"
Schmidt moved for approval, Mayne seconded, unanimous approval.
- BU#3142** 05-20 "*Production and characterization of mice lacking a pepsinogen F gene*"
Schmidt moved for approval, Beerntsen seconded, unanimous approval.
- BU#2070** 05-21 "Antibody dependent enhancement of West Nile virus infection of mice"
Schmidt moved for approval, Beerntsen seconded, unanimous approval.
- BU#9022** 05-22 "BSL-2 Laboratory Certification for Prostate Cancer Research"
Schmidt moved for approval, Beerntsen seconded, approval-one opposed.
Parsons explained that this protocol is mostly BL1 work-but some BL2. The room facilities and lab structure are good but ventilation is an issue. Beerntsen (IBC primary reviewer) commented work will be in hood and these are not pathogenic strains of bacteria. In order to obtain material from ATCC this researcher must have BL2 approval. Parsons will conduct training prior to

material being delivered to the lab Riddlemoser commented that this lab meets BL2 requirements according to BMBL recommendations Sanders expressed concern that approving this researcher for BL2 sends a message to ATCC that this researcher may receive other BL2 material. Sanders asked if the University is considering guidelines for researchers who have labs off campus? What sort of control does the University have over these rented/leased laboratory locations? This is the second protocol approval for an off campus location before the committee this year. Steve Hincey/Campus Facilities met with Roy Parsons and toured the facility and deferred to Roy for protocol recommendation.

- BU#2086 05-23 *"AAV Vectors for Spinal Muscular Atrophy Therapy"*
Beerntsen moved for approval, Schmidt seconded, unanimous approval.
- BU#2087 05-24 *"Transgenic Animal Laboratory"*
Schmidt moved for approval, Beerntsen seconded, unanimous approval.
- BU#3423 05-25 *"Genetically modified mice"*
Schmidt moved for approval, Mayne seconded, unanimous approval.
- BU#4076 05-26 *"AAV for Airway Gene Delivery"*
Schmidt moved for approval, Beerntsen seconded, unanimous approval
- BU#3426 05-27 *"Cloning genes for RNAs and eukaryotic proteins into bacterial plasmids"*
Schmidt moved for approval, Mayne seconded, unanimous approval.
- BU#Applied 05-28 *"Thyroid stimulating hormone predicts scan intensity in canine thyroid carcinoma"*
Mayne moved for approval, Beerntsen seconded, unanimous approval.
Parsons commented that this protocol did not require IBC approval;
however, the researcher's grant funder requested an IBC risk assessment.
- BU#Applied 05-29 *"Plant and bacterial recombinant DNA"*
Beerntsen moved for approval, Mayne seconded, unanimous approval.

Old Business

NIH & BMBL Guidelines for MU BSL-2 Construction

Riddlemoser reported that a working group has been meeting to develop guidelines for campus BL2 labs. The group plans to make a presentation during the November IBC meeting. The group is reviewing NIH as well as BMBL guidelines.

New Business

Annual protocol renewal on-line

About to begin the annual IBC protocol renewal process. It will be an on-line renewal as it has been the previous two years. Riddlemoser asked committee members if they would consider making Introduction to Biosafety class offered by EHS a required class for all researchers and workers in BL2 or higher laboratories. Riddlemoser stated that we would follow guidelines established for other EHS programs----initial training must be face to face and then renewal training every three years can either be done face to face or on-line.

2005-2006 committee members

Meeting packet included the new 2005-2006 Committee Membership List.
Mayne requested that her work phone be added to the listing.

Open Discussion

Parsons informed members that he has several protocol applications in process and should be sending them to members for review soon.

Sanders asked for a report from Parsons concerning the periodic lab inspections of all MU labs BL2 and above. He also asked for a listing of laboratory inspections Parsons has done in 2005.

Nanotechnology in Campus Research

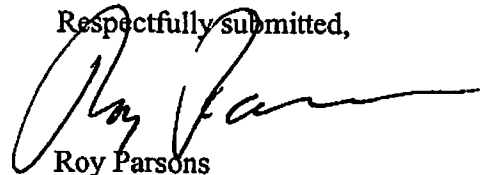
Riddlemoser informed members of a nanotechnology workshop he recently attended and provided members with some information from that workshop in today's meeting packet. Concerns with this research are biotoxicity and biocompatibility. NIH is requiring researchers to submit a plan; however, NIH has no guidelines for this type of work. Riddlemoser believes there are three MU researchers looking into this type of research. Beerntsen commented that these protocols should go to the IRB or ACUC rather than this committee. Riddlemoser asked members to contact EHS if they become aware of a researcher planning this type of research.

Next IBC Meeting Dates

- November 15, 2005 3:30PM in Room #12 RPDB
- January 17, 2005 3:30PM in Room #12 RPDB
- March 21, 2005 3:30PM in Room #12 RPDB

The meeting was adjourned at 4:20PM

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Roy Parsons', written over the typed name.

Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE

May 18, 2005 3:00PM

Room #12 Research Park Development Building

Members Present

Brenda Beerntsen, Vice Chair
Steve Hincey
Steven Kleiboeker
Katharine Mayne
Roy Parsons
Michael Rovetto
Frank Schmidt
Richard Tsika

Guests Present

Bill Dale, Ex Officio
Rob Hall
Pamela Gruer
Roger Riddlemoser

Members Absent

Arthur Karr, Jr., Chair
Lon Dixon
Charles Sanders

Brenda Beerntsen, Vice Chair, called the meeting to order at 3:00 p.m. with the required quorum in attendance.

Review 3/31/05 Meeting Minutes

Beerntsen asked for a motion to approve the March 31, 2005 IBC minutes. Mayne moved for approval of the minutes, Rovetto seconded, and the motion was approved unanimously.

Review of Approved Protocols

Review of Protocols Approved Since the Last Meeting

The committee packet included a listing of all protocols submitted for this committee's review since the 3/31/05 meeting. A total of five protocols were reviewed: Four protocols required full committee review. *The remaining protocol required the IBC Chairman and Biosafety Professional's review and approval.*

- BU#6079** 05-14 "Measures and Mechanisms of Muscle Pain in Humans"
Parsons reported—Blood Borne Pathogen Training and the lab inspection are complete. A low temp freezer is in place and a spill kit is available. Members discussed the room location listed on the protocol documentation. Parsons stated he has discussed carpet issues & cleaning---occupational exposure issues have also been addressed. Mayne questioned moving sampling equipment. Parsons explained that blood draws must be prepared and placed in cold storage within 10 minutes. He also commented that vinyl floor covers have been placed in the blood draw area and prep room. Mayne questioned the number of people involved in the protocol---Parsons responded 30 subjects total over a two year period. Mayne expressed concern about approving this protocol with the current research location---this sets a presedent Beerntsen was IBC primary reviewer and had concerns about the location; however, she felt approval was appropriate.
- BU#2100** 05-12 "Anterograde & Retrograde Tract Tracing in Rats"
- BU#1152** 05-13 "Meiotic Silencing by Unpaired DNA"

BU#4081 05-15 "Modulation of Endogenous Murine Proteins in Cell Lines"
BU#8021 05-16 "Blood Collection in Association with Exercise Research"
Parsons reported—Blood Borne Pathogen Training was done yesterday.
Hencey commented this research facility is also marginal for BL-2 work—
some ventilation issues

Old Business

NIH & BMBL Guidelines for MU BSL-2 Construction

Roger Riddlemoser, Roy Parsons, Peter Ashbrook, Steve Hencey, and Beth Asbury (Facilities Planning & Development) met earlier this year and discussed NIH & BMBL guidelines for MU BSL2 construction. Today's meeting packet included notes from the meeting. Hencey stated that new facility construction guidelines are well established; however, the need is to establish guidelines for labs being renovated. Riddlemoser stated he would again leave the issue as an agenda item for the committee meeting in September and hopes to have a presentation for the November meeting. Guidelines need to be pulled together so that a generic standard can be established for laboratory remodeling for the MU campus. Hencey stressed to members that the difficulty is that an area originally built to use as administrative space may (in the future) seem like an ideal laboratory space—trying to renovate administrative offices into laboratory space and still meet NIH & BMBL guidelines is the challenge.

New Business

Annual Testing Security Plan---More Information

The meeting packet included a copy of Department of Health and Human Services regulation 42 CFR 73.11 which specifies that a security drill be conducted annually. Parsons explained that this regulation focuses on security of select agents. EHS staff will watch how other University's handle this regulation. A drill will need to be scheduled by 2006. Schmidt asked if this practice drill would require that we include emergency responders or simulate a terrorist attack. Parsons commented that we are still trying to interpret the regulation.

Open Discussion

Hall recommended that an article be distributed to committee members in today's meeting packet. The article is a bioethics paper from Science Magazine "Ethics: A Weapon to Counter Bioterrorism". Hall explained that the article give the example of a Texas researcher that was doing what he wanted rather than follow regulatory guidelines and everything went wrong.

Riddlemoser informed committee members that he will attend a Regional Biocontainment Laboratory planning meeting tomorrow and one agenda item is communication with the community. He provided members with a copy of the current communications plan. The information included a list of community members that will be contacted---Riddlemoser asked IBC members for additional groups/individuals that should be added to the list. Smith suggested the Department of Health & Department of Agriculture be added to the list. Schmidt suggested DNR & City of Columbia Public Workers---disposal issues. Hencey reported that the plans may

go public this fall but the University is making sure that funding is in place before a public announcement is made.

Dale distributed a draft of the "Standard policy on OHSP requirements when working with animals (or animal tissues or fluids) and Vaccinia or other Orthopoxvirus". Dale will present the draft to the ACUC to see if they will approve the policy. The policy was created because an MU researcher needed this guideline for his research activities and the NIH and CDC guidelines are not clear. Additional policies of this type will need to be developed as researcher's plan to work with other pathogens.

Next IBC Meeting Dates

To be scheduled---September 2005.

The meeting was adjourned at 3:55PM.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Roy Parsons", written over the typed name.

Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE

January 26, 2005 3:00PM

Research Park Development Building

Members Present

Brenda Beerntsen, Vice Chair

Lon Dixon

Steve Hincey

Steven Kleiboeker

Roy Parsons

Michael Rovetto

Charles Sanders

Frank Schmidt

Chris Smith

Richard Tsika

Guests Present

Peter Ashbrook

Bryan Ross

Rob Hall

Roger Riddlemoser

Members Absent

Arthur Karr, Jr., Chair

Katharine Mayne

Brenda Beerntsen, Associate Chair, called the meeting to order at 3:00 p.m. with the required quorum in attendance.

Review 11/17/04 Meeting Minutes

Beerntsen asked for a motion to approve the November 17, 2004 IBC minutes. Dixon moved for approval, Sanders seconded, and the motion was approved unanimously.

Review of Approved Protocols

Review of Protocols Approved Since the Last Meeting

The committee packet included a listing of all protocols submitted for this committee's review since the 11/17/04 meeting. A total of eight protocols were reviewed: Four protocols required full committee review and two of those protocols are pending the committee's decision today. Four protocols required the IBC Chairman and Biosafety Professionals review and approval.

BU#2074 04-25 "West Nile Virus: Impact/influence on mosquito fitness"
Construction continues in the lab to create a negative airflow in Connaway Hall Room 19 & 20. The rooms will be renumbered after the construction is complete. Since the research is being handled at an elevated BL2 level, Hincey agreed that the work could be done in this lab.

BU#3614 04-24 "Handling of food-borne pathogens in food safety research (2004)"
Previous protocol of similar title (02-39) involved animals and was closed 5/17/2004. This research will not involve animals.

BU#3240 04-23 "Cis-sequences and trans acting factors in eukaryotic ribosome biogenesis"

BU#2101 04-22 "PCR assays for screening cell lines and biologic materials"

BU#2054 04-26 "AAV-mediated gene therapy in canine muscular dystrophy (2004)"

BU#4017 05-01 "Altering protein expression in cultured cells"

The final two protocols listed needed full committee review and action. Beerntsen asked for a motion to approve protocols listed. Dixon moved for approval, Parsons, seconded, and the motion was approved unanimously.

Pending protocols

BU#3147 "Characterization of genes and proteins in animal models of disease"
Protocol mailed to members earlier this week--Primary Reviewer/Frank Schmidt
Schmidt stated the protocol included some human cell lines. Schmidt recommended approval of the BL2 submitted protocol under NIH standards. Hencey commented he had not completed a review of the protocol submission. Hencey is concerned about BL2 guidelines for BMBL vs. NIH. Schmidt expressed confusion about which guideline this committee is expected to follow. Committee discussed need for clarification for renovations and new construction on campus and if researchers submitting protocols in an older lab must upgrade capabilities of the lab. Hencey understands the need for clear guidance on building design guidelines. Schmidt moved for approval of the protocol, Sanders seconded, and the motion was approved unanimously.

BU#2085 "Teaching protocol for VPBIO 2210 microbiology for Health Sciences"
This protocol was received by the BSO and is included in the IBC meeting packet today. Parsons reported this researcher will not be aerosolizing material and the researcher has a spill kit on site. Parsons also reported that all preparation of material will be done prior to class---in class work will be mainly microscope work. Members noted that Appendix A-3 listed precautions. Hall will investigate if another group on campus should be responsible for review of "teaching" protocols. Sanders expressed concern for potential student exposure. Dixon commented that the microorganism list attached to this protocol includes microorganisms that are typically seen every day. Reilly will use two labs in the VMDL and the lab where the material will be propagated is a BL2 lab. Sanders asked that the two VMDL labs be listed on the protocol information. Dixon moved for approval, Parsons seconded, and the motion was approved unanimously.

Updates on previously approved protocols

BU#2003 04-08 "RNA interference as a novel anti-parasitic therapy"
Researcher is to submit protocol amendment when she is ready to begin including animals in her research.

Old Business

Annual Protocol Renewals

Reichel reported the annual renewal process was completed last week.

IBC Protocol Change or Modification Criteria & Guidelines

Member packets included an updated guideline for review. Two recommendations made by members during the 11/17/04 meeting were incorporated into the guidelines.

- 1) Application Name Change—requires EHS review but not IBC Committee review
 - 2) Biohazard Level Change—added to the listing
- Sanders moved for approval, Parsons seconded, and the motion was approved unanimously.

Lab Worker Vaccination Policy Development

Parsons reminded members that BU#2098 has an approved protocol and plans to work with Vaccinia virus. Parsons has contacted University Hospital Staff Health Services and the Boone County Health Department to see if they could provide the vaccinations. Hall expressed concern if staff are allowed to sign a waiver—are we comfortable in insisting that staff be vaccinated? A good policy must be developed to work from. Dixon stated having this policy in place when the Regional Biocontainment Laboratory will be important.

New Business

Committee Member Information on EHS Website

Parsons displayed the new EHS website for members. Parsons questioned members if they had concerns with IBC committee member information posted on the site. A recommendation was made to add the EHS phone number to the site. Sanders asked that we use the EHS address for his listing.

Approve Emergency Response Document

Parsons explained that the Biohazard Emergency Response Procedures listed in the Biosafety Manual are still classified as “Interim”. The procedures are included in the meeting packet for today. Parsons asked members to review the document and send comments to his attention. He asked members to be prepared to discuss and hopefully approve this document at the next meeting.

Regional Biocontainment Lab

Hencey made a Powerpoint presentation with current design plans for the Regional Biocontainment Lab. Members discussed security risk issues for the facility.

Open Discussion

Current Events

Parsons included a recent newspaper article in the meeting packet. The incident occurred at Boston University and when their Institutional Biosafety Committee was notified of the incident they immediately stopped the researcher's work. Ashbrook explained that the researchers had thought they were using a vaccine strain of *f. tularensis*, when in fact the material was contaminated with a virulent form of the bacteria.

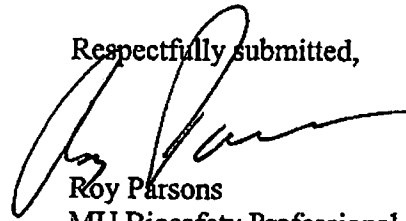
The LSC BSL3 lab began the commissioning process this week.

Next IBC Meeting Dates

- March 23, 2005 at 3:00PM in Room 12 RPDB
(UPDATED March 31, 2005 at 3:00PM in Room 572 LSC)
- May 18, 2005 at 3:00PM in Room 12 RPDB

The meeting was adjourned at 4:32PM.

Respectfully submitted,



Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE

March 31, 2005 3:00PM

Room #572 Life Sciences Center

Members Present

Arthur Karr, Jr., Chair
Brenda Beerntsen, Vice Chair
Lon Dixon
Steve Hincey
Steven Kleiboeker
Katharine Mayne
Roy Parsons
Michael Rovetto
Charles Sanders

Guests Present

Peter Ashbrook
Bill Dale, Ex Officio
Rob Hall
Bryan Ross

Members Absent

Frank Schmidt
Chris Smith
Richard Tsika

Jim Bixby/ Life Sciences Center escorted members through the BL3 lab at the Life Sciences Center.

Arthur Karr, Jr., Chair, called the meeting to order at 3:30 p.m. with the required quorum in attendance.

Review 1/26/05 Meeting Minutes

Beerntsen asked for a motion to approve the January 26, 2005 IBC minutes. Reichel reported that Hincey requested a correction to the minutes---Hincey abstained from voting on BU #3147 protocol since he did not have time to review it prior to the 1/26/05 meeting. Sanders moved for approval of the minutes with the Hincey correction, Hincey seconded, and the motion was approved unanimously.

Review of Approved Protocols

Review of Protocols Approved Since the Last Meeting

The committee packet included a listing of all protocols submitted for this committee's review since the 1/26/05 meeting. A total of ten protocols were reviewed or are currently in the review process: Five protocols required full committee review; two of the five are still pending the committee's final decision. *The remaining five protocols required only the IBC Chairman and Biosafety Professional's review and approval.*

BU#1148	05-04 "Analysis of Autophagy in Yeast"
BU#3146	05-05 "Germ Plasm mediated gene transfer using lentivirus as a vector"
BU#3234	05-06 "Bioinformatics Research for Undergraduates - teaching protocol"
BU#4074	05-07 "Laboratory research using human blood, urine and tracheal aspirate samples"
BU#Pending	05-10 "Control of Enterotoxin Gene Expression in S. aureus"
BU#Pending	05-11 "Function of the Bacillus anthracis core carbohydrate"
BU#3147	05-08 "Lentivirus Transgenics"
BU#5509	05-09 "Breast and Uterine Cancer Research"

Out to Primary Reviewers—Pending Committee Decision

BU#6079 “Measures and Mechanisms of Muscle Pain in Humans”
BU#2100 “Anterograde & Retrograde Tract Tracing in Rats”

Updates on previously approved protocols

BU#2003 04-08 “RNA interference as a novel anti-parasitic therapy”

Parsons reminded members that this researcher is to submit a protocol amendment when ready to begin including animals in the research protocol. There was no definite location for the animal portion of the research at the time that the protocol was approved. Dixon commented that the work will definitely be in the Lab Animal Center.

Old Business

Approve Emergency Response Document

Parsons reminded members that the Interim Biohazard Emergency Response Procedures document was distributed during the previous meeting and members were asked to review the document and send comments to Parsons. Parsons had no updates for the document. Hency & Mayne questioned how emergency responders are able to reach EHS. Ashbrook explained that EHS is in close contact with the Columbia Fire Department. MUPD has emergency contact numbers for EHS staff and will connect EHS staff with emergency responders on scene. Sanders commented that the document mentions reporting incidents; however, it doesn't make reference that a written report is required. Parsons will add a written report requirement for incidents involving biosafety level 2 agents that aerosolize.

Dixon moved for approval of the Emergency Response Document with the update recommended by Sanders, Sanders seconded, and the motion was approved unanimously.

Lab Worker Vaccination Policy Development

Dale explained that he had worked to develop an official policy based on RU #2098's usage and after consulting with other groups. These types of policies will need to be handled on a pathogen by pathogen basis. CDC recommendations will be used to develop guidelines. RU #2098's lab workers in direct contact with the pathogen are recommended to receive the vaccination and ancillary workers will receive recommended training. Dale consulted with Dr. Will Roland/University Hospital Medicine-Infectious Diseases, who recommends education but not requiring workers to receive the vaccination. Four staff are vaccinated and ready to go. The Office of Research pays for worker vaccinations.

NIH & BMBL Guidelines for MU BSL-2 Construction

Nothing new to report. Still working on guidelines for the University.

New Business

None

Open Discussion

NIH & CDC still don't have recommended containment levels for plants. Most are just being treated as BL1. The USDA & CDC published final regulations on 3/18/05. Soybean rust is now off the select agent list.

Ashbrook reported that final regulations published on 3/18/05 require a test of the security plan on an annual basis. Ashbrook and Parsons will provide more info at the next meeting in May.

Hencey reported that the University has put in a request for additional funds for the Regional Biocontainment Laboratory. If the additional funding is approved then the building could house two more labs and two more animal rooms.

Next IBC Meeting Dates

- May 18, 2005 at 3:00PM in Room 12 RPDB

The meeting was adjourned at 4:23PM.

Respectfully submitted,



Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE

November 17, 2004 3:30PM

Research Park Development Building

Members Present

Brenda Beerntsen
Lon Dixon
Arthur Karr, Jr., Chair
Steven Kleiboeker
Katharine Mayne
Roy Parsons
Frank Schmidt
Chris Smith

Guests Present

Peter Ashbrook
Bryan Ross

Members Absent

Steve Hincey
Michael Rovetto
Charles Sanders
Richard Tsika

Arthur Karr, Jr., IBC Chair, called the meeting to order at 3:30 p.m. with the required quorum in attendance.

New IBC member introduced:

Steven Kleiboeker/Veterinary Diagnostic Laboratory

Review 9/9/04 Meeting Minutes

Karr asked for a motion to approve the September 9, 2004 IBC minutes. Dixon moved for approval, Beerntsen seconded, and the motion was approved unanimously.

Review of Approved Protocols

Review of Protocols Approved Since the Last Meeting

The committee packet included a listing of all protocols submitted for this committee's review since the 9/9/04 meeting. A total of five protocols were reviewed:

All 5 required full committee review—1 protocol remains pending

BU#Pending

04-18 "Comparative efficacies of vancomycin, linezolid and BAL9141, a novel broadspectrum cephalosporin, in the treatment of methicillin-resistant staphylococcus aureus osteomyelitis: studies with a rabbit model"

Transportation of animals has stopped. Dixon commented staff are being trained. The transportation issue has been worked out. Animals will be transported from the Office of Animal Resources to the future diagnostic services area.

BU#2089

04-19 "Congenitally transmitted poxvirus infections"

BU#2089

04-20 "DNA vaccination against prenatal viral infections"

Both protocols for BU#2089 were approved. Animals will be challenged in Connaway Hall facility.

BU#2074

Pending "West Nile Virus, Impact/Influence on mosquito fitness."

This protocol remains pending. The BU is waiting on a renovation estimate to address airflow issues in the laboratory. The BU questioned some committee member's comments that the laboratory meet NIH guidelines; these guidelines would require additional renovations to the lab. Kleiboeker stated the 219A Connaway lab currently meets BMBL standards with no further construction updates. Parsons stated that the main lab still pulls negative but 219 Connaway is

positive Schmidt expressed concern that following NIH airflow standards would be very expensive for the University. Ashbrook suggested an outside consultant may be an option.

BU#1137 04-21 "Analysis of the role of the HuD protein in apoptosis"
Parsons reported ATCC requires this researcher's lab be BL2 to receive material. Schmidt questioned if we treat ATCC recommendations as our policy. He expressed concern that one day this requirement will be made for a lab that is not BL2

Updates on previously approved protocols

BU#2003 04-08 "RNA interference as a novel anti-parasitic therapy"
Researcher is to submit protocol amendment when she is ready to begin including animals in her research.

Old Business

Confidentiality Statements

Ross reported that the Office of Research has received signed Confidentiality Statements for all IBC members—including the newest member, Dr. Kleiboeker.

Annual Protocol Renewals

Reichel reported that an email message went to all researchers with an IBC approved protocol. Researchers were requested to log into the BioSafety Protocol On-Line Renewal site to update their active protocol(s). As of today's date only nine researchers have not completed the renewal process.

CWD testing at Vet Med Diag Lab

Parsons reported that the VMDL has delayed until fall 2005 plans for testing samples from deer population for Chronic Wasting Disease. The samples will be submitted by the MO Department of Conservation. The VMDL would also like to be able to do BSE testing.

New Business

Lab Worker Vaccination Policy

Parsons explained that a new researcher to the University has requested information on lab worker vaccination policy. No policy is in place—Parsons plans to develop a draft policy and present that policy to members during the January 2005 meeting. Dixon reported that the Office of Animal Resources has guidelines in place for their staff. Mayne commented that some workers may not have a choice, when areas they work in could contain potential diseases that could affect the community.

IBC Protocol Change or Modification Criteria & Guidelines

Member packets included draft guidelines for review. Schmidt noted that the guidelines require a new application when a "Protocol Name Change" is requested. Beerntsen asked why the protocol should be run through the full committee again. Schmidt and Dixon recommended a generic protocol title---big title that covers entire work for the researcher. Schmidt suggested an

additional category be added to the guidelines "Biohazard Level Change"---this change would require committee approval. These guidelines will be reviewed again during the January 2005 meeting

Open Discussion

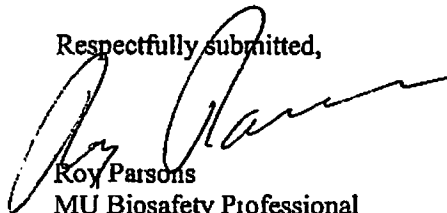
BU#3614 Submitted a Biohazardous Material Application. This researcher's protocol was previously approved but included an animal model. The researcher has returned to In Vitro work and is requesting this committee's approval. Schmidt moved for approval, Beerntsen seconded, and the motion was approved unanimously

Next IBC Meeting Dates

- January 26, 2005 at 3:00PM in Room 12 RPDB
- March 23, 2005 at 3:00PM in Room 12 RPDB
- May 18, 2005 at 3:00PM in Room 12 RPDB

The meeting was adjourned at 4:58PM.

Respectfully submitted,



Roy Parsons
MU Biosafety Professional

INSTITUTION BIOSAFETY COMMITTEE

September 9, 2004 3:00PM

Research Park Development Building

Members Present

Brenda Beerntsen
Lon Dixon
Steve Hincey
Arthur Karr, Jr., Chair
Roy Parsons
Charles Sanders
Frank Schmidt
Richard Tsika

Guests Present

Peter Ashbrook
William Dale
Robert Hall
Bryan Ross

Members Absent

Katharine Mayne
Chada Reddy
Michael Rovetto
Chris Smith

Arthur Karr, Jr., IBC Chair, called the meeting to order at 3:00 p.m. with the required quorum in attendance.

Two new IBC members were introduced:

Richard Tsika/Veterinary Biomedical Science
Steve Hincey/Campus Facilities Project Manager

Review 4/22/04 Minutes

Karr asked for a motion to approve the April 22, 2004 IBC minutes. Sanders moved for approval, Beerntsen seconded, and the motion was approved unanimously.

Review of Approved Protocols

Review of Approved Protocols

The committee packet included a listing of all protocols submitted for this committee's review since the 4/22/04 meeting. A total of ten protocols were reviewed:

8 required full committee review

**2 required only the IBC Chair and Biosafety Professional's Review/rDNA BL1 protocols

BU Pending # 04-18 "Comparative efficacies of vancomycin, linezolid and BAL9141, a novel broad-spectrum cephalosporin, in the treatment of methicillin-resistant staphylococcus aureus osteomyelitis, studies with a rabbit model"

Parsons reported the original protocol was submitted on 6/7/04; however, the BSP asked this researcher to update the following items: additional lab equipment, lab inspection, complete SOPs, and staff training. Parsons has completed the lab review and commented the lab manual is impressive. The BU has updated his protocol application and the updated application is included in materials distributed to the committee today

BU#3107 04-09 "Nutrition & infectious disease resistance"

****BU#9036** 04-12 "Agronomic practices for plant-made pharmaceutical tobacco"

BU#3203 04-10 "Phase display for breast & ovarian tumor imaging agents and biomarkers"

BU#3203 04-13 "Selection of tumor avid peptides in mice"

****BU#2048** 04-11 "In vivo transfection of mouse intestinal epithelium with adenovirus vectors"

BU#2084 04-14 "Molecular biology of mycoplasmas"

BU#3227 04-15 "Steroid receptor function"

BU#3821 04-17 "LSC 10 liter fermentor"

BU#3121 04-16 "Fat-1 transgenic pigs"

Updates on previously approved protocols

BU#2074 04-06 "Characterization of malaria sporozoite genes expressed in the mosquito"
Protocol approved by IBC on 2/27/04 with stipulations: researcher's laboratory must be approved by the BSP and laboratory staff receive appropriate training. On 7/28/04 an email message was sent to IBC members stating that the BSP had inspected and approved the researcher's lab on 7/22/04 and Parsons has completed lab staff training. The researcher's material has not yet been ordered, still pending attorney approval.

BU#2003 04-08 "RNA interference as a novel anti-parasitic therapy"
Committee's approval stated researcher must submit amendment when she moves out of the lab. Parsons contacted researchers on 8/5/04 and reaffirmed researcher will contact him prior to moving out of the lab.

BU#3614 02-39 "Handling of food-borne pathogens in food safety research"
Dixon reported that the FDA approved rendering the research animals. The main issue was compounds injected into research animals could not be allowed into the food chain. Parsons presented data from BU #3614's field samples. Nothing turned up on the samples.

Old Business

Confidentiality Statements

Today's meeting packet includes a Confidentiality Statement which committee members were asked to sign and give to Reichel before leaving this meeting. Dr. Hall reminded members that information discussed in this meeting and information in protocols distributed for this committee's review include proprietary and sensitive information that must be kept within this committee.

IBC Charter Update: Section III, Point 4

The IBC Charter was approved during the April 2004 meeting with some minor changes to Section III, Point 4. Ashbrook asked that the complete approved charter be distributed to members as we begin this new committee year—charter included in meeting packet distributed today.

New Business

NIH guidelines for IBC Meeting Minutes

In May 2004 the National Institutes of Health Biotechnology Activities Office distributed IBC meeting guidelines for Members and Staff of Institutional Biosafety Committees. These guidelines include information concerning: Preparation of IBC Minutes & Access to IBC Minutes. Hall commented the University is researching open meeting guidelines. This committee may need to close a future meeting if a member of the public is present and there is a need to discuss proprietary information. Tsika asked if members of the public had rights to request clarification during a meeting. Sanders stated his understanding is that the public may attend but not comment.

Appoint new IBC Assistant Chair

Dr. Brenda Beerntsen has agreed to serve as IBC Assistant Chair.

Biosafety Manual Updates

Meeting packets included several update recommendations to the Biosafety Manual. Parsons commented on several of the updates. Dixon asked how researchers would be notified of these updates. A recommendation that researchers completing annual protocol renewals could be notified of Biosafety Manual updates with a short letter documenting the changes.

Parsons displayed and explained signage information that is included in the Biosafety Manual update and would be posted outside animal laboratories. This signage is designed to protect staff unfamiliar with animal housing areas. Committee members were confused by the High/Low information on the forms. Schmidt made recommendations concerning the signage. Dixon made note of the recommendations and will bring it to the attention of the ACUC. Members questioned custodial & maintenance staff access to labs--custodial services for BL3 labs are provided by lab staff and maintenance staff entering BL3 labs are escorted.

Sanders made a motion to approve the Biosafety Manual updates with recommendations made by Schmidt, Beerntsen seconded, and the motion was approved unanimously.

Training Requirement for Laboratory Workers

Parsons recommended that workers in BL2 or higher labs be required to attend training: Introduction to Biosafety and Biosafety Update training every three years. This is similar to requirements for Hazardous Material Workers and Radiation Safety Workers. Parsons also recommended that all BL3 staff receive annual training. Sanders moved for approval, Dixon seconded, and the motion was approved unanimously.

Annual Protocol Renewals

Informed committee members that annual IBC protocol renewal process will begin soon. The renewal will again be an on-line process.

Annual Training for IBC Members

Ashbrook provided a shortened version of a program presented to this committee by Bob Hashimoto, Biosafety Consultant, in September 2003. This was meant to be a reminder for continuing members and initial training for new committee members.

Open Discussion

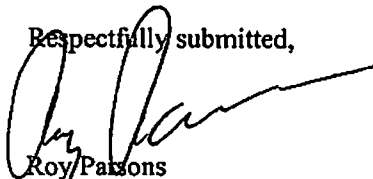
Beerntsen asked if a protocol was in place to assist researchers with documents requiring University administrative signature prior to ordering material. Ashbrook does not feel that this type of protocol exists but did recommend that researchers address documents to EHS first. This will allow EHS to track the documents through the signature process---through General Counsel and then back to Business Services. Members recommended that training for research staff include information on how to contact EHS to assist in obtaining University administrative signatures.

Next IBC Meeting Dates

- November 17, 2004 at 3:30PM in Room 12 RPDB
- January 26, 2005 at 3:00PM in Room 12 RPDB
- March 23, 2005 at 3:00PM in Room 12 RPDB
- May 18, 2005 at 3:00PM in Room 12 RPDB

The meeting was adjourned at 4:35PM.

Respectfully submitted,



Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE

April 22, 2004 3:00PM

Dalton Cardiovascular Research Center Library

Members Present

Brenda Beerntsen
Lon Dixon
Arthur Karr, Jr., Chair
Katharine Mayne
Roy Parsons
Michael Rovetto
Charles Sanders
Frank Schmidt
Chris Smith

Guests Present

Peter Ashbrook
William Dale
Bryan Ross

Members Absent

Elmer Price
Chada Reddy

Arthur Karr, Jr., IBC Chair, called the meeting to order at 3:00 p.m. with the required quorum in attendance.

Review 2/27/04 Minutes

Karr asked for a motion to approve the February 27, 2004 IBC minutes. Rovetto moved for approval. Mayne seconded, and the motion was approved unanimously.

Review of Approved Protocols

The committee packet included a listing of all protocols submitted for this committee's review since the 2/27/04 meeting. All three protocols listed were previously distributed for full committee review. The protocol submitted on 4/16/04 by BU #2003 has not yet been voted on by this committee. Dr. Dixon was chosen as the IBC primary reviewer. He informed committee members the researcher had incorrectly marked yes to Question #2 on the protocol application—this correction was made to the protocol form distributed with today's meeting packet. Dixon stated *Ascaris suum* is NOT a select agent. He also commented the animal feces will not have infective materials and animals in the study will be euthanized and incinerated at the end of the project. Parsons stated he had inspected this researcher's lab and Karr made a motion to approve this protocol with a stipulation that the researcher submit an amendment to her protocol when she moves out of the lab. Dixon seconded, and the motion was approved unanimously.

Old Business

Update on Protocol #02-30 BU #3614

Dixon informed members that approximately five weeks ago he contacted the USDA/FDA concerning the appropriate disposition of animal subjects involved in this research protocol. His understanding is that all animals will either need to be rendered or incinerated. Dixon has requested a written response from the regulatory agency. He is still waiting for an answer and will update the committee at the next meeting on the final disposition of the animals.

Confidentiality Statements

Ross stated he has confidentiality statements for committee members to sign. Ashbrook suggested holding these statements until new members join this committee in September.

Draft IBC Charter for Approval

Ashbrook presented an IBC Charter for this committee's review during the February 2004 meeting. He received several comments, updated the document, and redistributed the charter to members prior to this meeting. Sanders made a recommendation concerning Section III, Point 4, to conduct a "periodic" review rather than an "annual" review. Sanders stated that the NIH guidelines require a periodic review of all rDNA protocols and went on to say that he felt this periodic review should include an onsite review of the lab. Sanders suggested the IBC specify the period of years these onsite reviews should be conducted.

- Schmidt expressed his concern that if we establish these periodic reviews, then we must specify what we expect from researchers during these reviews.
- Ashbrook suggested that Parsons could go through the annual renewals and summarize types of protocols and present that information to the committee annually.
- Parsons stated that there are approximately 50 protocols at biosafety level 2 and estimated that less than 12 were rDNA
- Parsons and Ashbrook will discuss what "periodic" review means and provide additional guidance at the next meeting of this committee
- Sanders stated that he felt strongly "a paper review will not ensure NIH compliance".

Karr made a motion to accept the IBC Charter but amending the following for Section III, Point 4: "conduct a periodic review of all protocols involving the use of nonexempt rDNA to ensure compliance with NIH guidelines." Sanders seconded, and the motion was approved unanimously.

Annual Protocol Renewal Status—Finalized

Parsons reported that the annual protocol renewal process, which began in September 2003, has been completed. During the February 2004 meeting Parsons reported that BU #3230 was the only researcher that had not completed the annual renewal process. A letter was sent to the researcher's department chair and the researcher was given a response time limit of 30 days. The researcher met this requirement.

BL2 and BL3 Laboratory Security

Parsons presented laboratory survey results for BL2 and BL3 labs on the Columbia campus. Parsons commented NIH guidelines specify BL2 laboratories must have locking doors. Parsons went on to say many animal laboratories are keycard access; however, the biologicals are just not there yet. He did point out the survey results show almost all agent storage areas were locked.

Update on IBC protocol #04-06 BU #2074 (lab status)

BU #2074 reported updates to the lab are done and staff need to attend bloodborne pathogen training. The parasites are not in yet and an incubator will be ordered tomorrow. Parsons has been to the lab to check progress several times. Once training is complete for staff and the lab is ready to begin work, a final approval letter will be sent from this committee. Members of this committee will be informed of the status of the lab and training via email.

Update on Regional Biocontainment Laboratory

Dixon reported the only change in plans for this facility since this committee's last meeting is the building will be closer to the ASRC. Ashbrook reported he had additional copies of the Campus Master Plan which show the proposed location of the Regional

Biocontainment Laboratory. Ashbrook will send copies of the Campus Master Plan to the three community members of this committee. Dixon recommended this agenda item be removed since funding for the project will not be available this year and probably not the following year.

New Business

Select Agent Status Info

Parsons told members any references to Select Agents in information related to this committee must be carefully maintained. There is no need to go back to censor this information but before any requested release, this information must be removed. Parsons asked members to properly dispose of any information they may have, including any emails with information on researchers using select agents.

Training Requirement Proposal

Parsons informed committee members he would like their input concerning training requirements for lab workers in certain biosafety containments and working with rDNA. Parsons will present draft of recommendations to members during this committee's next meeting.

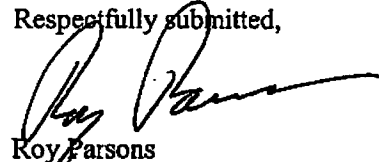
Open Discussion

Next IBC Meeting Date

September 9, 2004 @ 3:00PM in Room #12 RPDB.

The meeting was adjourned at 4:15 p m

Respectfully submitted,



Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE

February 27, 2004 3:00PM

Research Park Development Building

Members Present

Brenda Beerntsen
Lon Dixon
Arthur Karr, Jr., Chair
Katharine Mayne
Roy Parsons
Michael Rovetto
Charles Sanders

Guests Present

William Dale
Robert Hall
Mary Reichel
Bryan Ross
BU #3614 (researcher)

Members Absent

Elmer Price
Chada Reddy
Frank Schmidt
Chris Smith

Arthur Karr, Jr., IBC Chair, called the meeting to order at 3:00 p.m. with the required quorum in attendance.

Protocol amendment request for BU#3614

BU#3614 was in attendance, however, another researcher collaborating with this researcher, BU#3111, was unavailable. Parsons had previously asked both researchers to attend this meeting to provide specific information to this committee on a protocol involving research animals, which was not previously approved by the IBC or ACUC.

- Parsons explained that this committee had previously approved protocol #02-39 submitted by BU#3614 in 2002 but the protocol submission did include work with animal subjects. Research is already underway involving animal subjects. Parsons stated he has had frequent interactions with BU#3614 over the past few months and that this researcher has been cooperative during his review. This researcher submitted an amendment request for protocol #02-39 in January 2004. BU#3614 explained that she has been collaborating with BU#3111 for this protocol and that she was responsible for the biochemistry and BU#3111 was to supply the animals for the research.
- Mayne noted that BU#3614 had marked Select Agent on the protocol amendment presented to this committee---this was incorrect.
BU agreed to correct the protocol submission.
- Dale asked if any of the control animals received O-157:H7. BU#3614 explained that the amendment was only for E. coli, not Salmonella or Listeria. Dale also asked this researcher to edit the protocol to include rectal swabs instead of biopsies and include PPE for splatter protection for workers.
BU stated she would make this change to the protocol.
- The committee had a lengthy discussion concerning the disposition of the animals. The researcher stated that the current disposition plan is to continue a probiotic and hay for two additional weeks, complete testing to make sure that the animals are clean, and finally, send the animals to be slaughtered. Several members of the committee were concerned about this disposition plan and felt that the animals should not enter the food chain. Members discussed the possibility of sending these animals to a diagnostic lab or rendering company.
Dixon volunteered to explore disposition possibilities and will report back to this committee at the April 2004 meeting.
- Karr recommended approval of this protocol as long as both researchers follow guidelines discussed during this committee meeting.
All IBC members present approved. No members present abstained from the vote.

Review 12/3/03 Minutes

Karr asked for a motion to approve the December 3, 2003 IBC minutes. Rovetto moved for approval. Sanders seconded, and the motion was approved unanimously.

Old Business

Confidentiality Statement

During a previous meeting, members discussed the need for a confidentiality statement for members who review protocols submitted to this committee. Dr. Hall distributed a confidentiality statement developed for members of the Institutional Review Board (IRB). Members agreed that this statement would also be adequate for this committee and asked that Hall update the confidentiality statement so that it is specific for IBC committee members.

Hall agreed to present an updated confidentiality statement specific to this committee at the next meeting.

New Business

Sunshine Project request

Hall informed members that the University received a request for copies of previous meeting minutes for this committee. The University's General Counsel is handling the request; however, Hall commented that IBC Committee Meetings are open to the public and that this committee may need to consider closing future meetings to public visitors when sensitive issues are to be discussed

- Sanders asked Hall to see if this committee can close a meeting if a visitor is present and the committee needed to discuss an incident or protocol of a sensitive nature
- Dale recommended that investigator's names be kept out of this committee's minutes, possibility referring to the investigator as the PI.

IBC Subcommittee Meeting 1/23/04 & Report

Ashbrook reported that the IBC subcommittee consisting of himself, Roy Parsons, Frank Schmidt, Brenda Beerntsen, and Arthur Karr, Jr. Chair had met on January 23rd. Ashbrook commented that this group was organized to review recommendations made by Biosafety Consultant, Bob Hashimoto, during his visit in September 2003.

- One of Hashimoto's suggestions was to update the committee charter. Ashbrook took suggestions from the subcommittee's meeting and Hashimoto and drafted a committee charter which he has distributed to IBC members. Ashbrook asked members to carefully review the charter. He stated the charter includes a description of committee member responsibilities, a description of Primary Investigator responsibilities, and a change in the committee quorum requirement---specifically, 50% plus one is considered a quorum.
- Ashbrook also took time to go over the protocol review procedures listed in the draft charter. These procedures are intended to:
 - Clarify guidelines about who must review and who is able to approve each specific type of protocol submission. Set guidelines for each type of review: BL1 rDNA protocols vs BL2 protocols. Ashbrook comments that these new guidelines may require this committee to meet more frequently.
 - Clarify what is a protocol minor vs. a major protocol modification and who can approve the changes.
 - If the protocol contains proprietary information the PI must bring this to the attention of the Biosafety Professional at the time that the protocol is submitted for review---possibly by attaching a cover letter. This would allow the committee to give special attention to the protocol and only discuss and vote on the protocol during closed door sessions.
- Ashbrook asked Hall if he would discuss the information under "Appeals" with Jim Coleman/Vice Provost of Research to be sure that he also agrees with the statement there. *Ashbrook asked that members review the proposed charter, send suggestions to his attention, and he will present the final version to members for a vote during the next IBC meeting.*
- Ashbrook stated that Hashimoto's recommendations also included the need for a human gene therapy expert to serve as a member of this committee. Ashbrook asked members to contact him if they have a recommendation

Annual Protocol Renewal Status

Reichel informed members that the 2003 Annual Protocol Renewal is almost complete. Parsons and Reichel have made numerous attempts to contact BU#3230 including several email messages, voice mails, speaking with a researcher who has a laboratory near BU#3230's lab, and contact with a worker who states she no longer works in the lab. Karr instructed Reichel to address a letter to BU#3230's departmental chair, with a copy to the researcher, explaining that she has 30 days from the date of the letter to complete her annual protocol renewal or this committee will require that she resubmit her protocol for reapproval.

Parsons will inform IBC members of RU#3230's response during the next meeting of this committee.

Review of approved protocols since last meeting

The committee packet included a listing of all protocols submitted for this committee's review since the 12/3/2003 meeting. Three protocols on the listing required action:

- Protocol #02-39 was discussed earlier during this meeting with BU#3614 present during the discussion.
- Protocol #04-04 submitted by BU#9009 was previously distributed for committee review. Dixon was selected as primary reviewer and gave members information concerning this protocol. Dixon made a motion to approve, Parsons seconded, and the protocol was approved unanimously.
- Protocol #04-06 submitted by BU#2074 was previously distributed for committee review. BU#2074 explained that she is following guidelines of Environmental Containment Policy and specifically described modification being made to her lab to address containment. Dixon made a motion to approve, Sanders seconded, and the protocol was approved unanimously. It should be noted that BU#2074 was present during this meeting but abstained from this vote.

Open Discussion

Sanders questioned current University standards for BL2 and BL3 laboratories. Sanders recommended that all BL2 or BL3 laboratories be required to have self-closing, locking doors. Beerntsen expressed concern that busy labs do need an easy in and out access; however, when staff in the lab are working with a pathogen the access to the room should be locked. Ashbrook stated he would work with Parsons to conduct a review of these labs to see what is current practice on campus.

Ashbrook will present the results of the review at the next meeting of this committee.

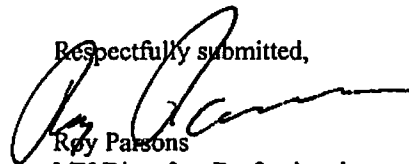
Dixon informed members that a meeting was held earlier today to discuss plans for the Regional Biocontainment Laboratory. Dixon stated that this committee should be involved in the review and approval of plans for the building as early as possible. Ashbrook stated that he and Parsons had also attended the meeting and will request that Jude Wawrzyniak advise architects and engineers involved in the project that this committee will need to be kept well informed of this project.

Next Meeting

April 22, 2004 at 3:00 p.m. in the Dalton Library

The meeting was adjourned at 4:45 p.m.

Respectfully submitted,



Roy Parsons
MU Biosafety Professional

INSTITUTIONAL BIOSAFETY COMMITTEE MEETING

December 3, 2003 1:00-2:30 PM

Research Park Development Building

Members Present

Brenda Beerntsen
Lon Dixon
Arthur Karr, Jr., Chair
Katharine Mayne
Roy Parsons
Elmer Price
Michael Rovetto
Charles Sanders
Frank Schmidt

Members Absent

Chada Reddy
Chris Smith

Guests Present

William Dale, ex-officio
Robert Hall
Roger Riddlemoser
Bryan Ross

Welcome Dr. Rovetto—New Member

Karr welcomed Michael Rovetto, the newest IBC member in attendance

Review 9/16/03 Minutes

Karr requested comments on the minutes from the previous IBC meeting held September 15, 2003. Schmidt requested a correction of one statement that he made concerning the protocol review response time. The second sentence under that subject should state, "Schmidt asked if the Biosafety Professional (BSP) and the Chair of the IBC (not the committee) could approve BL1 and BL2 protocols rather than completing a full committee review before their work could begin." Dixon made a motion to approve the 9/16/03 minutes with the correction stated today, Beerntsen seconded the motion. All members were in favor of approval.

Protocol Reviews

- **Additional Comments Concerning Protocol Review Motion by Dr. Schmidt**

Schmidt wanted to reintroduce his motion from the previous meeting—That the BSP and IBC Chair be given authority to approve BL1 and BL2 protocols rather than completing a full committee review before researcher could begin. Karr commented that he and Parsons are already reviewing and approving BL1/rDNA protocol submissions. Dixon commented that the ACUC uses a subcommittee to review and approve some of their protocol submissions. Schmidt commented that his main concern is that protocols submitted to this committee for review must be able to complete the review process quickly. Schmidt moved that a subcommittee of this group be formed to evaluate the protocol review process.

- **Statistics on Protocol Review Response Times**

Information on protocol review response times since the 9/16/03 IBC meeting was distributed.

- **Annual Protocol Renewal Status**

Information on researchers who have not yet completed their annual protocol renewal was distributed.

CDC Select Agent Application Status

Parsons reported that the University has received a Select Agent Permit approval from CDC for applicable researchers on campus. Schmidt asked that the Office of Research communicate the approval status to the campus community.

Confidentiality Statements

Dr. Hall stated that he would bring this information to the next meeting of this committee.

ATCC Process

Parsons informed committee members that ATCC is frequently updating their forms and asking for much more information from researchers about their labs. Parsons suggested that researchers start the ATCC

paperwork even before a protocol is approved. Schmidt asked if the ATCC form could be delegated to someone else for signature rather than Administrative Services. Parsons explained that the form is very specific about signature authority. Mayne expressed her concern that a lab may receive BL2 material prior to IBC and laboratory inspection approval. Committee members agreed that any BL2 material received for a researcher with an unapproved protocol or laboratory could be stored temporarily in another BL2 approved lab. The IBC must ensure that a researcher's work can move forward as well as assuring the general public, the University, and researchers are protected.

Policy on Disposal of Genetically Modified Animals

Dr. Dixon distributed the new policy on Disposal of Genetically Modified Animals to all members present.

Request for Volunteers for Focus Group

Riddlemoser informed members that EHS staff have begun to take a good look at the departmental website and are working on improvements to the site. He asked for any volunteers from this committee who might be willing to serve on a focus group to offer input on updates to the site. Dale stated that he would be willing to serve on the focus group.

Biosafety Manual

Riddlemoser reminded members that on February 11, 2003 this committee had adopted the MU Biosafety Manual "as an interim guide for one year pending comments during that period." Riddlemoser gave a short presentation explaining minor changes made to the manual during the past 10 months. Riddlemoser asked if the committee would be willing to make a motion to finalize the manual with the changes stated. Schmidt made a motion for final approval of the MU Biosafety Manual including the updates Riddlemoser had outlined today, Dixon seconded the motion. All members were in favor of approval.

"60 Minutes" Tape

At the request of EHS Director, Peter Ashbrook, IBC members viewed a short news segment aired by the CBS network. The "60 Minutes" news story outlined an FBI criminal investigation involving the loss of 30 vials of potentially deadly plague bacteria from Dr. Thomas Butler's laboratory at Texas Tech University. Members discussed the actions taken by Dr. Butler and the FBI investigation.

Open Discussion

- Mayne explained that she had been selected as IBC Primary Reviewer for a protocol which Dr. Chris Lorson had submitted—"Standard Cloning & Biochemical Expression of Epitope-Tagged Proteins in E. coli & Eukaryotic (human, mouse) Cell/Tissue culture". Mayne has reviewed the protocol and clarified some incorrect information—no live animals or humans will be used. Mayne made a motion to approve the Larson protocol, Schmidt seconded the motion. All members present voted their approval.
- Dixon reported that a contractor has been selected to build a BL3 facility on the east side of campus. He stated that plans are underway to inform the community.
- Dixon informed members that in February 2004 there are plans for a desktop exercise—a cattle foot & mouth outbreak drill.

This meeting was adjourned at 2:30PM.

INSTITUTIONAL BIOSAFETY COMMITTEE MEETING
Research Park Development Building, Room 12
September 16, 2003

Member Present

Arthur Karr, Jr. Chairman
Brenda Beermtsen
Lon Dixon
Katharine Mayne
Roy Parsons
Elmer Price
Chada Reddy
Charles Sanders
Frank Schmidt
Chris Smith

Members Absent

Michael Rovetto

Guests Present

Peter Ashbrook
William Dale, ex-officio
Robert Hall
Robert Hashimoto, consultant
Roger Riddlemoser
Bryan Ross

Welcome new member

Karr welcomed Katharine Mayne, the newest member in attendance.

Introduction Bob Hashimoto

Peter Ashbrook, EHS Director, introduced Bob Hashimoto, Biosafety Consultant. Ashbrook worked with Hashimoto to set up an on-site visit to review the MU Biosafety Program. Hashimoto spent yesterday and today meeting with EHS staff and researchers involved in the Biosafety Program

Review 4/14/03 minutes

Karr requested comments on the minutes from the previous IBC meeting held April 14, 2003. Beermtsen requested correction of several minor spelling errors. Dale stated his comment on the second page of the minutes should have read "that researchers must have animal protocols listed on cage cards". Reddy made a motion to approve the 4/14/03 minutes with the corrections stated today and Schmidt seconded the motion. All members were in favor of approval.

Select Agent Update

- **CDC Inspection & Application Status**

Ashbrook informed members that a consultant hired by the CDC visited the MU campus during May in response to MU's Application for Laboratory Registration for Possession, Use and Transfer of Select Biological Agents and Toxins. Ashbrook stated that the consultant recommended updates to 15 different items on the application. Updates were made and the CDC consultant was satisfied with the application. A CDC representative contacted Ashbrook one month ago requesting that MU document that the campus is in compliance with CDC guidelines. Ashbrook will respond this week and he expects this will be the last hurdle before final CDC approval.

- **Handling of security risks/stolen keys**

Parsons informed members that a researcher recently dealt with a serious security issue in a lab when a worker in his lab lost his keys. Staff responded quickly and appropriately and the lab was rekeyed prior to 5PM on the same day that the keys were lost.

- **Francisella Tularensis**

Parsons informed members that Francisella Tularensis was discovered in research animals in two separate labs on campus. Lab staff contacted EHS as soon as the organism was discovered. All CDC and MU requirements for reporting and disposal were met and Ashbrook stated that the CDC was pleased with our response.

Schmidt expressed his "continual confusion" regarding select agents and the fact that this listing is periodically updated and researchers are expected to be aware of new agents added to the list.

Protocol Review Response Time

Schmidt explained that he had submitted a protocol for IBC review which took over one month to

complete the review process. Schmidt asked if researchers could approve BL1 and BL2 protocols rather than completing a full committee review before their work could begin. Karr commented that he and Parsons have already worked out a system to approve BL1 rDNA protocols without a full committee review. Schmidt made a motion that "The IBC grant the IBC Chair and the BSP authority to give (correction 12/3/03—at IBC meeting 12/3/03) researchers administrative approval to begin work requiring BL1 or BL2 conditions prior to receiving a formal committee approval." Dr. Reddy seconded the motion. Committee members discussed Dr. Schmidt's motion.

- Hashimoto commented that NIH guidelines require a review of all rDNA protocols. Hashimoto went on to mention that some campuses have a separate committee to review rDNA protocols.

Schmidt restated his motion that "The IBC give trained researchers administrative approval to begin work at the BL1 or BL2 level when the research does not involve the use of recombinant DNA material."

Members present had a lengthy discussion concerning:

- the length of time that a full IBC protocol review takes
- that delays of up to one month will work against the researcher
- the need for another investigator to review BL2 protocols
- possibility of changing committee charter
- defining procedures to expedite reviews for certain organisms or certain circumstances
- defining procedures for protocol amendments

Dr. Karr asked that members send comments concerning this discussion to his attention.

Schmidt made a motion to table his motion until the next meeting, Katherine Mayne seconded the motion. All were in favor.

CONFIDENTIALITY STATEMENTS

Karr stated that many official University committees require that members sign confidentiality statements. Having IBC members sign confidentiality statements would help to assure researchers that information submitted for protocol review would be kept confidential. Dr. Hall/Office of Research will work with Reichel to distribute confidentiality statements to committee members for their review and signature.

STANDARD FORMAT FOR IBC PROTOCOL REVIEW PROCESS

Parsons stated that will be working on a check off sheet to be available at the time IBC members review a protocol. The check off sheet would focus on the laboratory setting where the research will occur: are biosafety cabinet that will be used for the research inspected and up to date and what types of disinfectants will be used. Parsons will also require that researchers begin including a scope of work in their protocol submissions.

Hashimoto recommended that the scope and expertise of this committee be enlarged. He recommended that this committee assess which departments are submitting more protocols. Departments requiring more of the committee's time should be asked to support the committee by assigning a staff member from their department that can participate as a member of the committee. Having this member on the committee would also mean that the new member could take the lead on reviewing protocols submitted by his/her own department. Hashimoto also commented that this committee has the right to request a consultation from an outside consultant if there are questions concerning a protocol during the review process.

DR. ESTES LAB CLOSURE (BL3 LAB)--FAICLITY MODIFICATION

Parsons informed committee members that Dr. Mark Estes has left the University. Parsons stated that the Estes lab was properly decontaminated and that Dr. Kleiboeker is now using the lab. Dr. Kleiboeker is doing diagnostic work with the West Nile Virus right now.

OHSP UPDATE

An agreement with Staff Health Services (SHS) has been reached. SHS will begin seeing OHSP

animal care workers for medical assessments in the next week or two. OHSP forms are being updated and the number of animal care workers participating in the OHSP program will begin increasing again

OPEN DISCUSSION

Dr. Dixon announced that the Office of Animal Resources has created a policy on the Disposal of Transgenic Animals. Dixon explained this policy was developed in response to an issue that occurred at another institution last summer. Transgenic animals must not get into the animal or human food chain. Dixon is getting this policy out to the campus community through the ACUC and IBC. Dixon will send this policy to Reichel for distribution to IBC members.

The Vet School is actively seeking funding for BL-3 work. The Vet School is currently assessing some available space in Connaway Hall, possibly converting the laboratory into a BL3 facility for West Nile research. This is only in the works, it may not happen.

This meeting was adjourned at 4:35PM.