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Texas A&M University
Research Park

May 25, 2006

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

Dear Mr. Hammond:

Per your request, attached are the minutes of the Texas A&M University's
Institutional Biosafety Committee (IBC) since May 1, 2003.

If you have any questions or need additional information, please contact me at
(979) 847-9362, or by e-mail at araines@vprmail.tamu.edu.

Sincerely,

Angelia Raines
Director,
Office of Research Compliance

Attachment



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University

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INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

OCTOBER 9, 2003

MINUTES

MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Tom Ficht Van Wilson Mike Buckley Sara Jordan (ex-officio member) Mark Parenti (ex-officio member) Mark Hurt (ex-officio member) Brent Mattox Bert Kretzschmar		Tim Phillips Jon Skare Jimmy Keeton Patricia Klein Vernon Tesh Karin Lum Rabbi Peter Tarlow Kathy Warren	Matt Voss

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:50 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments	<ul style="list-style-type: none"> Dr. Ficht Discussed Comments at the CPI meeting this month about the new IBC form. The new form has been edited and adjusted and the committee believes that it is appropriate. The University needs an accounting of where these BL2 labs are located. 	<ul style="list-style-type: none"> Tom and Van will draft a letter a letter to PIs and we will send a note to all BL2 labs about filing IBC registration.
Approvals since last meeting	<ul style="list-style-type: none"> Approved as noted 	
Approvals on new form	<ul style="list-style-type: none"> Approved as noted 	
Temporary Approvals	<ul style="list-style-type: none"> Research Compliance has sent out notes to PIs that they have 15 days to submit. 	<ul style="list-style-type: none"> Kalli will follow up with PIs
Protocols in Pending	<ul style="list-style-type: none"> As noted. 	
IPGS	<ul style="list-style-type: none"> Matt Voss discussed IGPS capabilities to email committee members directly from site and to approve applications with electronic signatures. 	<ul style="list-style-type: none"> Matt will update IGPS to include these capabilities.
Next IBC Meeting	<ul style="list-style-type: none"> January 13, 2004, Tuesday, 11:30-1:30pm 	
ADJOURNMENT	The meeting adjourned at 1:15 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

JANUARY 13, 2004

MINUTES

MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Brent Mattox Jimmy Keeton Tom Ficht Vernon Tesh Mike Buckley Van Wilson Kathy Warren Decna Wallace	Dianne Cornett Kalli Schendel	Patricia Klein Jon Skare Rabbi Peter Tarlow Tim Phillips Karin Lum Sara Jordan (ex-officio member) Mark Hurt (ex-officio member)	Matt Voss

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:50 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments - Mike Buckley	<ul style="list-style-type: none"> Discussion/Approval of October 9, 2003 Meeting Minutes Introduction of IBC Chairs and Committee members. Questions about IPGS, its use and follow up. 	<ul style="list-style-type: none"> Approval to accept minutes was moved and 2nd, minutes passed as presented.
CDC Inspection – Mike Buckley	<ul style="list-style-type: none"> 	<ul style="list-style-type: none">
Member Status – Mike Buckley a. Sara Jordan b. Karin Lum	<ul style="list-style-type: none"> S. Jordan will continue to review IBC applications via IGPS. K. Lum graduated and moved, and recommended Brandon Hudder as her replacement. The Chairs would like to review and make recommendation to REE about B. Hudder as the replacement. Background/checking with the student's chair/the graduate student council will all be done. 	<ul style="list-style-type: none"> Chairs recommend that we seek resumes from potential members. To Do: Send a note to the Graduate Student Body President for potential members for IBC.
Protocol Update – Dianne Cornett a. Pending b. Approved c. Temporary Approval(s)	<ul style="list-style-type: none"> Current IBC applications were briefly discussed. Pending updates as described in the meeting. Approved updates as presented Temporary approvals as presented. 	

Update – Revisions and/or Changes to IBC Application – Kalli Schendel a. Processing of Protocol Revisions – Time Limit For Investigators b. Processing of Protocol Amendments c. Signature Page Requirements	<ul style="list-style-type: none"> • There was a brief discussion about the changes to the application – moving from pdf to word, and the use of smaller fonts as listed. • Signature approval sheet goes with the original packet. • E Coli checkbox – there is no need for a checkbox, it needs to be moved. 	<ul style="list-style-type: none"> • Matt will work with the chairs on this issue.
Update – Revisions and/or Changes to IGPS – Kalli Schendel a. Processing of Protocol Revisions – Time Limit For Investigators b. Processing of Protocol Amendments c. Signature Page Requirements	<ul style="list-style-type: none"> • Kalli presented changes to IGPS status. • There were several changes to IGPS suggested. • M. Voss suggested that he put tabs up for internal viewing of acrobat files. • Right side of the pdf, there could be a list of the comments to the document. 	<ul style="list-style-type: none"> • M. Voss to implement the changes. • ORC will compile the comments made to the IPGS system and will forward all those comments to the chairs so they can make a decision on which comments should be addressed
Off-Campus or Other Protocol Review(s) – Mike Buckley a. Baylor College of Dentistry b. Lubbock (2003193 – Burow) c. Prodigene (2003218 – Howard)	<ul style="list-style-type: none"> • Who will provide certification of labs at Baylor? B. Mattox stated that the Baylor committee would be the 'certification' group for these labs. • Dr. Klein will be reviewing the Lubbock Issue. • Dr. Klein will also be working on this issue. 	
Date of Next Meeting – Mike Buckley	<ul style="list-style-type: none"> • The next IBC Committee meeting will be scheduled in April 	<ul style="list-style-type: none"> • Dianne will ask members for open dates in April.
Other	<ul style="list-style-type: none"> • Connection with EHS 	<ul style="list-style-type: none"> • A draft letter will be developed instructing EHS to let PIs know that IBC is required before a lab can be 'certified' operation.
ADJOURNMENT	The meeting adjourned at 1:30 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) APRIL 16, 2004 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Brent Mattox Mike Buckley Van Wilson Patricia Klein Rabbi Peter Tarlow Jimmy Keeton Mark Hurt (ex-officio member) Jon Skare Tom Ficht Vernon Tesh	Dianne Cornett Kalli Schendel Olivia Ash	Tim Phillips Karin Lum Kathy Warren Deena Wallace Sara Jordan (ex-officio member)	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:50 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments - Mike Buckley	<ul style="list-style-type: none"> • Discussion/Approval of January 13, 2004 Meeting Minutes • Introduction of IBC Chairs and Committee members. • Minutes were reviewed and approved. • Discussion about grad student representation on the committee. 	<ul style="list-style-type: none"> • Approval to accept minutes was moved and 2nd, minutes passed as presented. • Remove Karin Lum from the Roster. • The IBC office will contact members of the committee to nominate at least one student representative for the IBC. • The IBC office will contact the Graduate Student Council and request nominations for a Grad Student representative to the IBC.
Update on CDC Facility Inspection Report – Mike Buckley	<ul style="list-style-type: none"> • The response has been sent to the CDC • The IBC is setting up a tracking mechanism to follow up on the CDC observations • Cyber Security issues 	<ul style="list-style-type: none"> • The CDC report will be tracked and the IBC office will ensure tracking and completion of all of those items. • Dr. Ficht has requested that we have Al Elrod look at the IBC office's computers to see if we can add security certificates to the Groupwise mail servers in the hope this will provide for more security of our electronic email systems.
Protocol Update – Dianne Cornett a. Pending b. Approved c. K-12 Issue	<ul style="list-style-type: none"> • Pending approvals are being moved thru the process. • K-12 issue – the IBC office is requesting permission to require the K-12 users to complete the IBC form – there are 5 from previous request who have not filed the new IBC form. 	<ul style="list-style-type: none"> • The IBC has approved the handling of the K-12 issue as outlined by the IBC office. • Non-response by a PI after 30 days will also be copied to the department head. • The IBC would like for the IBC office to follow up with the research administrations groups to ensure that grants are being checked to ensure that compliance issues are being approved before

		<p>grants are approved.</p> <ul style="list-style-type: none"> It was recommended that if a PI will not comply with the requirements of the IBC that the department head be notified, and if non-compliance continues, the research administration is contacted for a possible hold on funding until PI is in compliance.
Review Draft Amendment Form – Dianne Cornett	<ul style="list-style-type: none"> The draft amendment form was briefly reviewed and discussed. 	<ul style="list-style-type: none"> It was requested and agreed that Committee members will forward any suggested changes or revisions to the amendment form to the IBC office for coordination of a revised draft.
Review / Discuss Draft of Autoclave Guidelines – Dianne Cornett	<ul style="list-style-type: none"> Discussion about what is needed from Autoclave guidelines. The thought was that we need oversight of this issue. EHS is inventorying the autoclaves on campus and developing a program to ensure the proper inspection of autoclaves. The thought was that the BL3 facilities and the LARR facilities should be first on line; others would be placed in order depending on risk. 	<ul style="list-style-type: none"> The IBC is requesting EHS to develop guidelines for autoclave inspection and use. The IBC is requesting that the SBAT facilities and LARR be completed first with areas of higher risk completed next. B. Mattox will develop a protocol for distribution about autoclave functioning.
Discuss Revisions and / or Changes to IBC Application – Dianne Cornett / Kalli Schendel	<ul style="list-style-type: none"> There was a discussion about the IBC application, updating the application, and the Occupational health program – the EHS office is coordinating this effort. The worker's compensation is also available to employees. The IBC office requested for each committee member to look over the document, and those members with specific expertise to look at those sections of the application and provide feedback on suggested changes or revisions. 	<ul style="list-style-type: none"> Committee members will provide comments on the form from a general perspective as well as a specific perspective. Issue about Occupational Health Program – the EHS office will be developing a program of Occ Health across the entire university. This should be implemented shortly. It was requested and agreed that Committee members will forward any suggested changes or revisions to the application form to the IBC office for coordination of a revised draft.
IGPS Status – Kalli Schendel	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> IGPS reviews should be completed in question format if the reviewers would like specific questions answered by a PI before approval.
Date of Next Meeting	<ul style="list-style-type: none"> 	<ul style="list-style-type: none"> The IBC office will coordinate the next meeting which will be in May.
ADJOURNMENT	The meeting adjourned at 1:30 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MAY 21, 2004 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Brent Mattox Mike Buckley Van Wilson Patricia Klein Rabbi Peter Tarlow Jimmy Keeton Mark Hurt (ex-officio member) Jon Skare Tom Ficht Vernon Tesh	Dianne Cornett	Tim Phillips Kathy Warren Deena Wallace Sara Jordan	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:50 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> • Discussion/Approval of April 16, 2004 Meeting Minutes • 	<ul style="list-style-type: none"> •
Update on CDC Facility Inspection Report – Mike Buckley	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> •
Protocol Update – Dianne Cornett a. Pending b. Approved c. Deactivation Notices	<ul style="list-style-type: none"> • Pending approvals are being moved thru the process. • 	<ul style="list-style-type: none"> •
Student Representative Status – Dianne Cornett	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> •
Committee Membership Terms – Mike Buckley	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> •
Irradiation Services – Mike Buckley	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> •

Autoclave Guidelines – Tom Ficht/Brent Mattox	•	•
Status of Revised Forms – Dianne Cornett a. IBC Application b. IBC Amendment	•	•
Other	•	•
Date of Next Meeting	•	• The IBC office will coordinate the next meeting which will be in .
ADJOURNMENT	The meeting adjourned at 1:30 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) JULY 2, 2004 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Brent Mattox Mike Buckley Van Wilson Jon Skare Tom Ficht Vernon Tesh Kathy Warren Deena Wallace Betsy Browder Sara Jordan	Dianne Cornett Olivia Ash Amanda Pietsch Bonnie Reid	Tim Phillips Patricia Klein Rabbi Peter Tarlow Jimmy Keeton Mark Hurt (ex-officio member)	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:55 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> Discussion/Approval of May 21, 2004 Meeting Minutes 	<ul style="list-style-type: none"> After noting a correction to list Sara Jordan under 'Members Not Present', no other changes were requested. Moved to accept, seconded and motioned approved with minutes accepted as provided.
CDC Status – Mike Buckley a. Updating/Adding Personnel b. Personnel Training	<ul style="list-style-type: none"> It was noted that the registration process is, for the most part, complete and that we are awaiting formalized CDC notification. It was restated that there will be some registration changes as soon as the formal notification is received, including an 'all persons, all locations' amendment. The committee was notified that the PI information letter is being finalized with a target date of August 1st. There was discussion regarding LARR personnel in SBAT labs and the need to have as much uniformity as possible in the common areas of training and security. 	<ul style="list-style-type: none"> The committee agreed that further discussions need to continue regarding the training of BSL3 visitors, including Physical Plant and outside vendors. A meeting will be scheduled with all active SBAT PI's to discuss this subject matter in more detail.
Protocol Update – Dianne Cornett a. Pending b. Approved	<ul style="list-style-type: none"> There are 30 protocols in pending since the May 21 meeting, the earliest date being 5/24/04. There have been 11 protocols approved since the May 21 meeting. 	<ul style="list-style-type: none">

c. Deactivation Notices	<ul style="list-style-type: none"> There are 3 protocols that have been sent deactivation notices since the May 21 meeting; 2 of those protocols involved PI's with BCOD, which is currently in the process of finalizing inspection procedures with EH&S for their facilities. 	
Student Representative Status – Dianne Cornett	<ul style="list-style-type: none"> Per a request made on behalf of the IBC, the GSC has been contacted and is in the process of recruiting an individual to fill this committee position. Sara Jordan stated that she would be heading this recruitment effort on behalf of the GSC. 	
Autoclave Guidelines Status – Brent Mattox	<ul style="list-style-type: none"> Autoclave guidelines have been posted on the EH&S website. EH&S will begin testing autoclaves mid-September. 	•
Status of Revised Forms – Dianne Cornett a. IBC Application i. Proposed Revision(s) Regarding Autoclave/Disposal Issues ii. Proposed Revision(s) to Attachment 'A' iii. IBC Amendment	<ul style="list-style-type: none"> There was discussion on revising the disposal tables within the IBC application to include a space for the location of the autoclave, including building and room number. Dr. Tesh volunteered to be part of the group assigned to finalize these areas of the application. The need to make a minor revision to Attachment 'A' was discussed and approved. We will add the verbiage regarding identification of animals, which is currently included in Section I.D. and Section II.D., to Section III of this attachment. Additional discussion took place regarding the possible need to add statements to Attachment 'B' regarding Occupational Health and Safety issues and a new Section IV for the use of <u>any</u> human cell lines. Further discussion on this topic is needed to determine how this will impact the current review process and the expansion of duties by the IBC. 	•
IBC Review Process – RG1/BSL1 Protocols – Mike Buckley	<ul style="list-style-type: none"> In order to streamline the IBC review process, it was recommended that RG1/BSL1 protocols be 'pre-reviewed' by the IBC chairs prior to being uploaded for 10-day review. This process will involve creating a new section on the application that will allow the Chairs to determine whether or not the protocol needs to be reviewed by the entire committee. 	•
IBC Annual Reviews/Inspection Process – Mike Buckley	<ul style="list-style-type: none"> It was discussed that an annual review and inspection process will need to begin this fall, starting with BSL3 labs (due to CDC registration) and adding BSL2 and BSL1 labs thereafter. 	<ul style="list-style-type: none"> An annual review form and inspection check list will be drafted and presented to the committee at the next scheduled meeting for review and discussion.
Ongoing Physical Repairs – BSL3 Labs – Brent Mattox	<ul style="list-style-type: none"> There was discussion regarding the status of physical repairs within BSL3 labs and that such repairs will be performed as needed on an ongoing basis. 	•

Other	<ul style="list-style-type: none"> The VPR office is developing a group from across the university to become knowledgeable about the import/export issues associated with the Dept. of State and the Dept. of Commerce. Most of this group attended training sessions by the Dept. of Commerce over the summer. <p>The goal of the group will be to take the information and develop some form of information to PIs to educate them about compliance with these important federal laws.</p> <p>Our target is to have this operationalized by Jan. '05.</p>	•
Date of Next Meeting	<ul style="list-style-type: none"> An email will be sent out to committee members asking for available dates for a meeting in August. 	•
ADJOURNMENT	The meeting adjourned at 1:00 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) AUGUST 20, 2004 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Brent Mattox Mike Buckley Van Wilson Mark Hurt (ex-officio member) Jon Skare Tom Ficht Vernon Tesh Deena Wallace	Dianne Cornett Amanda Pietsch	Tim Phillips Kathy Warren Betsy Browder Jimmy Keeton Sara Jordan Patricia Klein Rabbi Peter Tarlow	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:15 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> Discussion/Approval of July 2, 2004 Meeting Minutes 	<ul style="list-style-type: none"> Minutes were approved as presented.
CDC Status – Mike Buckley/Brent Mattox <ul style="list-style-type: none"> a. Registration Status b. FAQ Handout 	<ul style="list-style-type: none"> It was mentioned that the TAMU registration file has been assigned to a new CDC representative. The members were updated on the status of the current amendment filed on 7/27/04, which involved updating of the original registration paperwork, as directed by our CDC representative, in an effort to 'clean up' our file. In addition, this amendment also includes the addition of "all persons, all labs" as it pertains to CMP personnel and specific SBAT facilities. It was noted, however, that we are still awaiting final notification from CDC. The CDC has released a FAQ section on the SBAT program as regards regulations under 42 CFR 73 	
Protocol Update – Dianne Cornett <ul style="list-style-type: none"> a. Pending b. Approved c. Deactivation Notices 	<ul style="list-style-type: none"> 26 Protocols in pending; 21 protocols approved since the last meeting; 2 protocols have been sent deactivation notices; and 2 protocol amendments have been uploaded for review. 	<ul style="list-style-type: none"> Dr. Ficht requested that PI's be sent pending approval memos

Student Representative Status – Dianne Cornett	<ul style="list-style-type: none"> The Graduate Student Council has been contacted to submit names of individuals interested in serving on the IBC as a Student Representative. The committee requested that a résumé and CV be provided for each interested party. 	<ul style="list-style-type: none"> Forward résumés and CVs to Chairs for review.
Status of Administrative Forms – Dianne Cornett/Mike Buckley <ol style="list-style-type: none"> IBC Application IBC Amendment Draft of Lab Personnel Certification 	<ul style="list-style-type: none"> The IBC application has been formatted in Word, but is still awaiting revisions to the disposal tables within the various sections of the application as well as additional information regarding an occupational health and safety statement. The IBC amendment form was reviewed and approved for use. It was agreed that, with minor modifications, this certification will be added to Section III of the application. 	
IBC Annual Reviews/Inspection Process – Mike Buckley <ol style="list-style-type: none"> Draft of Annual Review Form Draft of Inspection Check List Inspection Calendar Discussion 	<ul style="list-style-type: none"> A draft of the IBC Annual Review Form was reviewed but no action was taken to approve the form as yet. A draft of the Inspection Check List was reviewed by the committee. It was agreed that the format will need to be reviewed by Brent Mattox before being utilized. It was discussed and agreed that completing inspections for BLS3+ labs would be a priority in getting this process implemented. An inspection team was formed and it was determined that the team would work towards utilizing the current ULACC inspection schedule so as to not interfere with research activities. 	
Other	<ul style="list-style-type: none"> NIH OBA Symposium is scheduled for September 21 – 22. A draft agenda for the conference was provided to the committee members. It was also noted that Mike Buckley would be attending this conference. A presentation by BEI Resources was presented to the University community on August 9, 2004. A copy of the presentation was provided to the committee members. 	
Date of Next Meeting	<ul style="list-style-type: none"> The IBC office will poll members to coordinate a date for the next meeting. 	
ADJOURNMENT	The meeting adjourned at 12:45 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
DECEMBER 9, 2004
MINUTES

MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Brent Mattox Mike Buckley Van Wilson Jon Skare Tom Ficht Vernon Tesh Deena Wallace Jimmy Keeton Sara Jordan Patricia Klein Rabbi Peter Tarlow Betsy Browder	Dianne Cornett	Tim Phillips Mark Hurt (ex-officio member)	Chis Meyer

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 1:40 p.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> Discussion/Approval of August 20, 2004 Meeting Minutes 	<ul style="list-style-type: none"> Minutes were approved as presented with the exception of adding Dr. Browder under 'Members Not Present' at August meeting.
Occupational Health Program Presentation – Chris Meyer	<ul style="list-style-type: none"> Chris Meyer provided a copy of the power point presentation regarding this subject matter (attached to meeting package). The goal is to target researchers or individuals working with animals initially and then possibly adding other areas in the future. Accreditation requires policies to be in place and the areas that are under this are a priority. Designed to work up front, as a preventative measure. Students on scholarships would benefit since they are not available to use WC. Theory is that each PI and the individuals within their labs will be required to complete an enrollment questionnaire and will be available to opt out. Questions on funding and how far the budget will take it through were presented, i.e. hard costs on medical fees associated with the program. 	<ul style="list-style-type: none"> The IBC agreed to support the program as presented. Betsy Browder motioned and Patricia Klein seconded. It was suggested that providing an option for cost sharing may be beneficial to the program as it is currently developed for animal work. Dr. Wilson to draft a letter of support.
Protocol Update – Dianne Cornett a. Approved b. Pending c. Deactivation Notices d. Amendments (Approved/Pending)	<ul style="list-style-type: none"> 28 Protocols have been approved since the last meeting; 14 protocols are pending; 2 protocols were administratively withdrawn (deactivated prior to approval status); 2 protocols have been sent deactivation notices; 2 protocol amendments have been approved and 2 protocol amendments are pending. 	<ul style="list-style-type: none"> Dr. Wilson had some questions regarding deactivated protocols and how that affects the researcher's protocol in general, i.e., canceling one aspect and continuing research in another. Follow up and discussion regarding this subject needs to take place with the IBC office.
CDC Status – Mike Buckley/Brent Mattox a. Registration Status	<ul style="list-style-type: none"> Submission of all requested paperwork by the CDC is complete. We're still awaiting approval or status of the registration. 	<ul style="list-style-type: none"> Brent to check with CDC on what they have on record as far as what is approved prior to the CDC inspection.

b. Mock Inspection	<ul style="list-style-type: none"> Representatives from UTMB have agreed to assist in a 'mock inspection' which is scheduled for 12/14. A copy of a draft itinerary was distributed for review. 	
IBC Annual Reviews/Inspection Process – Mike Buckley a. Inspection Calendar Discussion	<ul style="list-style-type: none"> It was determined that scheduling the IBC annual inspections for SBAT labs alongside the ULACC inspections, as originally planned, would not work due to the amount of time that ULACC spends inspecting non-SBAT labs would unnecessarily tie up too much of the IBC inspector's time. It was agreed that the inspections would have to be scheduled separately from the ULACC inspections. 	<ul style="list-style-type: none"> IBC Inspection Team will perform annual inspections during the scheduled 12/14 mock-inspection.
IBC Member Status – Mike Buckley/ Dianne Cornett a. Community Representative b. Student Representative(s) Update	<ul style="list-style-type: none"> Kathy Warren is no longer able to participate as a community representative since she took a job at the university. Resumes for Brandi Kutil and James Johnson were presented to the IBC for review. 	<ul style="list-style-type: none"> Members are encouraged to bring candidates to the table for consideration. Email re-commendations to Van Wilson.
Other (Hand Outs) a. Letter from DHHS b. News Article from Science magazine	<ul style="list-style-type: none"> Dr. Wilson brought forth discussion on cell culture work and whether or not it needs to be institutionalized, policies initiated and approved by the IBC. Further discussion at a future IBC meeting was requested. 	
Date of Next Meeting	<ul style="list-style-type: none"> The IBC office will poll members to coordinate a date for the next meeting, which will more than likely take place during the spring semester. 	
ADJOURNMENT	The meeting adjourned at 3:30p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) APRIL 7, 2005 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Betsy Browder Jan Faber Tom Ficht Mark Hurt Sara Jordan Jim Joyce Jimmy Keeton Brent Mattox Angelia Raines Frank Stein Vernon Tesh Van Wilson	Dianne Cornett	Jon Skare Patricia Klein Tim Phillips Rabbi Peter Tarlow	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 9:10 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> • Introduction of New Director of Research Compliance, Angelia Raines. • Discussion/Approval of December 9, 2004 Meeting Minutes 	<ul style="list-style-type: none"> • Minutes were approved as presented.
Protocol Update – Dianne Cornett <ul style="list-style-type: none"> a. Approved b. Pending c. Deactivation Notices d. Amendments (Approved/Pending) 	<ul style="list-style-type: none"> • 20 Protocols have been approved since the last meeting; 7 protocols are pending; 0 protocols were administratively withdrawn (deactivated prior to approval status); 1 protocol has been sent a deactivation notice; 4 protocol amendments have been approved and 4 protocol amendments are pending. 	
IBC Member Status – Van Wilson <ul style="list-style-type: none"> a. Announcement of New Members b. Community Representative Update 	<ul style="list-style-type: none"> • Frank Stein and Jim Joyce have been added to the IBC. Angelia Raines is replacing Mike Buckley and Jan Faber is replacing Deena Wallace. • As discussed at the meeting in December 2004, Kathy Warren is no longer able to participate as a community representative since she took a job at the university. It was noted that no candidate names have been forwarded to the Chair for review and consideration since December. Angelia Raines noted that she had a candidate that was interested in serving and would contact that individual to obtain a resume to submit to the IBC. 	<ul style="list-style-type: none"> • A resume of the individual will be circulated to the IBC and if there are no objections, the ORC will follow with a recommendation to the IBC.
CDC Status – Brent Mattox/Angelia Raines <ul style="list-style-type: none"> a. Registration 	<ul style="list-style-type: none"> • Brent updated the IBC on the current amendments that have been filed since the February inspection and also provided an update on inspection report. Dr. Tesh questioned the position of CDC and the realm of regulations that are being required. Brent noted that the BMBL guidelines are followed by the 	<ul style="list-style-type: none"> • Insure that all affected PI's are copied on any future requests for information from/to CDC.

<p>b. Inspection Report Status</p> <p>c. Federal Register – Final Rules Issued</p>	<p>inspectors and that if any of the observations noted seem unreasonable, we would argue our points to CDC. Jan Faber added that we have the right to take a legal stand on issues when necessary. Brent noted that all responses will be reviewed by the affected PI before they are submitted to CDC. Dr. Tesh would also like the PIs to be more involved in the process.</p> <ul style="list-style-type: none"> • ORC will take the lead in providing the IBC with any updates and clarifications regarding the Federal Register. 	
<p>IBC Policies and Procedures – Van Wilson/Tom Ficht</p> <p>a. Amendments</p> <p>b. Annual Reviews</p> <p>c. Responsibility of Autoclave Certification</p>	<ul style="list-style-type: none"> • Discussion pursued regarding how many amendments would be allowed within the 3 year approval process and the criteria for the scope of an amendment as it relates to the original research objective that was approved. • The annual review process needs to be started so that applications that have been approved for over a one year period can be re-reviewed. The form content was previously approved by the IBC. • There was continued discussion on the autoclave certification and testing requirements and the responsibility that the PI has in ensuring the effectiveness of the equipment being used whether the equipment is located within the PI's lab or within the department and/or building. Brent noted that EH&S's inspection program for autoclave certification is now operational. 	<ul style="list-style-type: none"> • ORC will take the lead on forming a sub-committee to work on establishing and finalizing the policies and procedures for amendments, annual reviews and revisions to the IBC form regarding autoclave testing and certification.
<p>IBC Registration of Cell Culture Work – Van Wilson</p>	<ul style="list-style-type: none"> • Dr. Wilson brought forth discussion on cell culture work and whether or not it needs to be institutionalized, policies initiated and approved by the IBC. Most issues regarding cell culture research falls under the human subjects regulatory requirements. The main issue would be whether or not the IBC needs to review this type of work as it regards the biosafety risk aspect. Education of the PI seems to be the first action needed to ensure that health and safety standards are met. 	<ul style="list-style-type: none"> • Further information on this subject matter will be researched and brought back to the IBC for future discussion.
<p>Other – Angelia Raines</p> <p>a. PRIM&R/IBC Basics Seminar Update</p>	<ul style="list-style-type: none"> • Angelia Raines noted that she and Dr. Browder attending the PRIM&R conference in early March including the portion of the conference related to IBC Basics. She noted that the OBA is aware of the need to expand the scope of training and guidelines so that they reach beyond more than just rDNA research. Everyone seeks guidance from the OBA and the OBA has plans to initiate an outreach training program. • Angelia stated to the IBC that the ORC will be undergoing some changes and has asked for names of individuals from the Research Committee who may be interested in serving on the various committees that may be established. 	
<p>Date of Next Meeting</p>	<ul style="list-style-type: none"> • The IBC office will poll members to coordinate a date for the next meeting, which will more than likely take place during the summer. 	
<p>ADJOURNMENT</p>	<p>The meeting adjourned at 10:30 a.m.</p>	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) AUGUST 24, 2005 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Jan Faber Tom Ficht Mark Hurt Sara Jordan Jim Joyce Jimmy Keeton Patricia Klein Brent Mattox Angelia Raines Jon Skare Frank Stein Rabbi Peter Tarlow Vernon Tesh Van Wilson	Dianne Cornett	Tim Phillips Betsy Browder Jan Jackson	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:45 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> Discussion/Approval of April 7, 2005 Meeting Minutes 	<ul style="list-style-type: none"> Minutes were approved as presented.
Protocol Update – Dianne Cornett a. Approved b. Pending c. Deactivation Notices d. Amendments (Approved/Pending)	<ul style="list-style-type: none"> From the time period of April 6 – August 11, 2005, 22 Protocols have been approved; 11 protocols are pending; 0 protocols were administratively withdrawn (deactivated prior to approval status); 1 protocol amendment is pending; 6 protocol amendments have been approved; 5 protocols have been deactivated (due to Annual Reviews); out of the 77 Annual Reviews sent out (through June), 45 have been processed/approved; 15 are pending; and 17 are awaiting response from the PI. 	
IBC Member Status – Van Wilson a. Community Representative Update b. Member Status/Commitments	<ul style="list-style-type: none"> New Community Representative, Jan Jackson, was unable to attend the meeting today due to a death in the family. Angelia Raines addressed the committee to request that if they have any other individuals that may want to serve on the committee as a non-affiliated Community Representative. Terms for all members will be set for 3 years with renewal on an annual basis. Sara Jordan suggested that all graduate students be considered for 1 year. Biosketches vs. CVs should be considered which is what is required to be sent to NIH or NSF (biographical sketches limited to a 2-3 page format). It was suggested to create a general template for committee members to use; possibly utilizing the format based on NIH grant requirements for new members. Committee appointment letters from Dr Ewing will go out within the next week. 	

<p>CDC Status – Dianne Cornett/Brent Mattox</p> <p>a. Inspection Report Update</p> <p>b. TAMU Biohazard Emergency Response Initiative (Drill)</p>	<ul style="list-style-type: none"> Regarding the CDC inspection update, the office has not received any additional responses since the submission in July requesting additional information. Regarding the New Federal Register, TAMU will be required to initiate biohazard drills within the Crisis Management Plan (CMP). Currently emergency type drills are already taking place across the campus, so the initial groundwork has already been established. Angelia Raines noted that the Office of Research Compliance is considering the creation of a sub-committee between the IBC, Patriot Act Task Force, and other necessary administrative units within the TAMU System to further the task of incorporating the biosafety hazard aspect to the current CMP. Brent noted that he is awaiting a response from FBI on 2 separate administrative amendments regarding the addition of lab personnel. As regards the amendment for the restructuring of the current ARO list, there was some discussion on how to submit the amendment since the changes include title revisions, removals and additions of ARO members. Angelia requested that Brent provide her with the form so the ORC can assist in the preparation of the paperwork for this amendment. Brent stated that he is currently communicating with CDC regarding the removal of one of the PIs, including the lab personnel assigned to work under this PI, who left TAMU to work at another university. There was discussion regarding the process for removal of a PI from the registration and the timing of the removal prior to the PI being approved at another entity. It was mentioned that the documentation of communications is very important. Brent also noted that EH&S is planning to update their website to include a separate page for Biological Safety. For now, the website has a link under Biological Safety which includes a brief description on how to apply for security clearance, which is the current procedure that is being followed by CDC and FBI. 	<ul style="list-style-type: none"> Brent to provide written procedure on how to remove a PI from the CDC registration process.
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<p>IBC Policies and Procedures – Van Wilson/Tom Ficht</p>	<ul style="list-style-type: none"> • There was minor discussion regarding the future implementation of InfoEd. • Discussion developed regarding K-12 strains vs. E. coli strains and how that is noted within the IBC application. Since K-12 strains are attenuated strains that do not survive well in the environment but have been approved for rDNA work, if the researcher uses K-12 strains exclusively, then this work can be exempt. Otherwise, if it is not noted, then it necessitates a higher level of concern. A check box to the table under Section VI needs to be added to distinguish if the strains are K-12 strains. • It was also suggested that a links to websites can be added to the application for the PI to access to determine whether or not the strains included on the application are of the K-12 variety. It was further suggested that if links are added to this section of the application, that it may also be helpful to add similar links to other sections to assist in determining whether organisms are pathogenic or not. The discussion continued on whether to ask the PI to submit evidence of due diligence to determine the pathogenicity of an organism. It was suggested that links within the application, e.g., CDC or Pub Med websites, could be provided for the PI to access, reference and verify, via a check box (or similar idea) within the table, the website reviewed for each organism listed. • There was also discussion on whether or not the plant attachment within the IBC application could be improved upon in the areas of containment and disposal methods. It was asked and Patricia Klein agreed that she would review the attachment and offer her comments on how the questions can be modified to benefit the PI and the reviewer. • A handout was provided by Angelia Raines on suggested autoclave guidelines that include definitive information on what is being required by the IBC. The main objective is determining the standard that the IBC is looking for. The discussion continued on reasonable methods of testing, how often and by whom. Once the standards or minimum expectations are established and approved by the IBC, Patricia Klein suggested that these be sent not only to the PIs but to the departmental level as well. • Additional discussion needs to be reopened regarding the possibility of training for PIs and lab personnel for proper usage of autoclaves and general best practices in laboratory safety. Brent Mattox stated that this training could be developed by EH&S. • Need to establish procedures for final approval of rDNA (anything not exempt) and blanket approval for exempt or BSL1 protocols. All others will have to be approved by the IBC at a regularly scheduled meeting. 	<ul style="list-style-type: none"> • Members to review portions of forms to see if there are any modifications that can be made to improve on the types of questions that are asked so that the information provided is what the reviewers are seeking. • Jan Faber to look into the validity of the Texas Administrative Code and to check on public information act/requirements for posting of public meetings. • Add location and building number for the location of the autoclave, and whether or not the autoclave is departmentally run or individually run to IBC application. • Need to develop minimum guidelines for protocols for proper usage. Angelia noted that either UC Davis or Washington State had websites that could be looked at for reference.
<p>IBC Registration of Cell Culture Work – Van Wilson</p>	<ul style="list-style-type: none"> • Dr. Wilson reopened the discussion regarding cell culture work. The IBC issue or perspective is whether or not the IBC needs to develop policies to register those who use cell lines, especially human and non-human primate lines. If so, Dr. Wilson noted that all would have to be handled at a BSL2 level unless it can be proven that the cell lines are not pathogenic. Dr. Ficht also questioned if human serum needs to be looked at as well. Ongoing discussion on this subject is needed. 	

<p>Other – Angelia Raines</p> <p>a. IBC Best Practices Seminar Update</p>	<ul style="list-style-type: none"> • Angelia Raines, Dr. Wilson, Dr. Ficht and Dr. Browder attended the IBC Best Practices Seminar in San Antonio last week. It was noted at the conference that future NIH site visits for outreach and instructional purposes can be expected. 	
<p>Date of Next Meeting – Van Wilson</p> <p>a. Meeting Calendar</p> <p>b. Membership Training & Orientation</p>	<ul style="list-style-type: none"> • Discussion of the necessity to schedule regularly monthly standing meetings. • It was discussed that there is a need to develop training for not only committee members but PIs as well. Web-based training modules would be ideal on an annual or semi annual basis and should include practical lab uses on autoclaves, rDNA issues, etc. in the training. 	<ul style="list-style-type: none"> • Dianne to send out email to committee asking for available times for each member in an effort to schedule regularly scheduled meetings for the fiscal year.
<p>ADJOURNMENT</p>	<p>The meeting adjourned at 1:55 p.m.</p>	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) OCTOBER 26, 2005 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Betsy Browder Jan Faber Tom Ficht Mark Hurt Sara Jordan Jim Joyce Jimmy Keeton Patricia Klein Brent Mattox Angelia Raines Jon Skare Frank Stein Vernon Tesh Van Wilson	Dianne Cornett Kena Rogers	Tim Phillips Jan Jackson Rabbi Peter Tarlow	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:45 a.m.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> • Discussion/Approval of August 24, 2005 Meeting Minutes • Discussion that the August minutes should reflect in more detail regarding the validity of the Texas Administrative Code and that Jan Faber is to check on public information act/requirements for posting of public meetings • Discussion that in future meeting minutes will need to reflect the number of voting members 	<ul style="list-style-type: none"> ▪ Tesh motioned to approve meeting minutes as presented. Sarah Jordan seconded.
Protocol Update – Dianne Cornett	<ul style="list-style-type: none"> • From the time period of August 12 – October 24, 2005, 9 Protocols have been approved; 13 protocols are pending; 0 protocols were administratively withdrawn (deactivated prior to approval status); 4 protocol amendments are pending; 6 protocol amendments have been approved; 7 protocols have been deactivated (6 due to Annual Review process); 59 Annual Reviews were sent out with 28 processed/approved; 12 pending; and 19 awaiting response from the PI. • Discussion regarding the deactivated protocols and the IBC deactivation notifications and procedures. The Principal Investigator, the Department Head, the Funding Agency, and the Research Foundation are notified. • Dr. Wilson opened for additional discussion on the approved proposals and annual reviews submitted. There was no further discussion 	<ul style="list-style-type: none"> ▪ Dianne will check on Sinden and Davis deactivated protocols. ▪ Dr. Wilson motioned to approve all protocols as presented. Dr. Klein seconded.

<p>IBC Policies and Procedures – Van Wilson/Tom Ficht</p> <p>a. Process for Review of rDNA Applications</p> <p>b. Revisions to IBC Application</p> <p>c. Amendment Process</p>	<ul style="list-style-type: none"> • Discussion regarding the process of rDNA Applications. Dianne presented the committee two options of how to process the incoming applications. Option 1 would consist of pre-reviewing the protocols and the committee electronically submits any comments regarding the protocol. The IBC will then may request that the PI may make any changes prior to the meeting. The revised application is then presented at the next IBC meeting. Option 2 consists of presenting the application at the IBC meeting and the committee members are open for comments and any changes that need to be made prior to approval at the convened meeting. Any major changes may require that the application is presented at the next IBC meeting for approval. • Dr. Browder suggested that it should be the committee members' prerogative to call the application to full committee review for open comments regarding any given application. • Discussion that the IBC continue to send 10-day review on every Monday opposed to the suggestion on sending them out as they come in to expedite the review process. PIs should submit proposals 10 working days prior to the committee meeting date. • A draft of the revised IBC application was presented to the committee by Dianne Cornett. • Dr. Klein stated that USDA should be included as a check box under the Funding Source and Routing Agency section of the application. Dr. Browder suggested separating Funding Sources and Routing Agency section into two separate sections. • There was discussion on updating the appendixes of the application particularly concerning the Biosafety Levels Discussion on the section under Autoclaves, the number of runs should be omitted from the application, and should only include the recommended testing frequency according to the Biosafety level. It was also discussed to include a section that will identify the location of the autoclave in the application for individually operated autoclaves. To change "It is important" to "The IBC requires" • There was also discussion in establishing a subcommittee regarding Select Agent work. It was suggested to have closed sessions after the IBC meeting is adjourned that only includes members that have participated in background checks. • Brent Mattox stated that the Definitions of Risk Group and Biosafety level appendix is important information that the PIs should know. Training is not currently available but could be developed and be available for PIs and lab personnel. Brent to work on forming some type of training. • Dianne called to the committee's attention regarding the number amendments that should be processed. It was suggested that the PI can only submit 2 amendments per year before having to complete a new IBC application. 	<ul style="list-style-type: none"> • Dr. Wilson motioned to remove the Co-PI information from the revised IBC application. • Add location and building number for the location of the autoclave, and whether or not the autoclave is departmentally run or individually run to IBC application. • The section including co-PI information should be taken off of the IBC application. It was decided that only one PI should be assigned to each protocol and the Co-PI information should not be added in the revised application. • Need to include assurance check under the requirement for the documentation of an autoclave waste treatment. • Input another column in the table in section VI.A.1 with the column heading being E.coli. • Dr. Browder to review the Animal attachment with a comparison group to edit the attachment for the next meeting. • Remove first table and add an organism box between the columns "Type of waste" and "Potential Hazard" in the table in Attachment C: Use of Plants, VI.A. Make Biological Materials row bigger to include a total of 3 rows for additional space for data entry.
<p>IBC Membership – Van Wilson</p> <p>a. Graduate Student Council</p>	<ul style="list-style-type: none"> • Dr. Wilson called to the committees' attention that the Graduate Student Council contacted the IBC office questioning if the IBC committee needs additional 	

Representation	graduate student representation. It was discussed that the IBC needs no additional graduate student representation on the committee at this time. If in the future that the IBC has a vacancy the IBC will contact the Graduate Student Council.	
CDC Status – Dianne Cornett a. Inspection Report Update	<ul style="list-style-type: none"> The VPR received a letter from the CDC, dated September 14, 2005, stating that the CDC does not require any further response at this time. 	
Other		
Date of Next Meeting – Van Wilson a. Meeting Calendar – November/ December Meeting Dates	<p>The remainder of the meetings, if needed, through FY '06 are tentatively scheduled as follows: *11/23, *12/21, 1/25, 2/22, 3/22, 4/26, 5/24, 6/28, 7/26 and 8/23.</p> <p>*Meeting dates for these months will need to be further discussed due to the holidays.</p> <ul style="list-style-type: none"> 	<ul style="list-style-type: none"> Dianne to follow up with the committee asking for available times for each member in an effort to schedule the meeting dates for November and December both months tentative dates may conflict with the scheduled Texas A&M holidays.
ADJOURNMENT	The meeting adjourned at 1:45 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) DECEMBER 1, 2005 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Betsy Browder Jan Faber Tom Ficht Sara Jordan Jim Joyce Patricia Klein Brent Mattox Angelia Raines Jon Skarc Frank Stein Vernon Tesh Van Wilson Victor Pantusa	Dianne Cornett Kena Rogers	Mark Hurt Jan Jackson Jimmy Keeton Tim Phillips Rabbi Peter Tarlow	David Phalen John Salsman

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11: 26 a.m. by Dr. Wilson.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> Dr. Wilson introduced the two guests present, Dr. David. Phalen and John Salsman. Dr. Wilson also introduced the new IBC member, Victor Pantusa. Dr. Wilson solicited any changes or revisions to the previous meeting minutes, no further comments were received. 	<ul style="list-style-type: none"> Dr. Tom motioned to approve meeting minutes as presented. Dr. Skarc seconded. Vote approved unanimously
Protocol Update – Van Wilson	<ul style="list-style-type: none"> The numbers reflected on the protocol update report, submitted in each meeting, were brought up for discussion. The current report reflects only the activity that has taken place since the last meeting. It was decided to maintain this format. 	<ul style="list-style-type: none"> Dr. Stein motioned to approve report as written. Vote approved unanimously

<p>Other Business</p> <p>a. Public Information Law</p> <p>b. CDC update – Inspection Process Status</p>	<ul style="list-style-type: none"> • Jan Faber distributed handouts to the committee in regards to the public information act. He reminded the committee that legislation dictates that any information generated in committee meetings is public information. Therefore, it was suggested that a separate and distinct security committee that is not governed by the Institutional Biosafety Committee be formulated, to allow information to be confidential. • Angelia suggested obtaining more information and identifying what other institutions are doing in regards to the Public Information Law. She also suggested that the matter be tabled at this proceeding, but placed on the agenda for continued discussion at the next IBC meeting. • There was brief discussion on deemed export information. Angelia stated that a group will be traveling to Washington in January to receive additional training on deemed exports. • Dr. David Phalen distributed a handout for the committee's review and discussed the Movement of donated birds from isolation to the <i>Schubot aviary</i>. Dr. Phalen was seeking suggestions from the committee in regards to the changes in his research how to handle the changes within the IBC process. Because the original diagnostic test were wrong and recent tests tested negative for mycobacterial infections, it was suggested for Dr. Phalen to submit an amendment change the protocol Biosafety Level from a 2 to a 1. • Angelia announced that Dianne is no longer at the IBC office; she has taken a position at the VPR office. However, she will continue to help out with CDC procedures on a temporary basis. Angelia expressed her thanks to Dianne for helping out. Angelia distributed hand outs of the audit guide for CDC inspections for the committee review. Dianne forwarded the latest schedule and itinerary of CDC inspections via e-mail. • Brent mentioned anyone on the IBC committee who wishes to inspect the LARR facility is required to take a TB test prior. Tests will be given at Occupational Health at Scott & White in College Station. 	
<p>Date of Next Meeting – Van Wilson</p> <p>a. Meeting Calendar –</p>	<ul style="list-style-type: none"> • Next Meeting Date: January 25, 2006 	
<p>ADJOURNMENT</p>	<p>The meeting was adjourned at 12:52 p.m.</p>	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) JANUARY 25, 2006 MINUTES			
MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Betsy Browder Tom Ficht Jan Jackson Jim Joyce Jimmy Keeton Brent Mattox Victor Pantusa Angelia Raines Jon Skare Frank Stein Rabbi Peter Tarlow Vernon Tesh Van Wilson	Tiffany Agnew Kena Rogers	Jan Faber Mark Hurt Sara Jordan Patricia Klein Tim Phillips	Shoshana Eitan

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11: 50 a.m. by Dr. Wilson.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/ FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> Dr. Wilson solicited any discussion or comments regarding the previous meeting minutes that were emailed to each committee member for prior review and also included in each member's folder. 	<ul style="list-style-type: none"> Dr. Wilson motioned to approve the minutes as presented and seconded by Dr. Browder. The motion was approved unanimously.
Review of Protocol Approval Process – Angelia Raines	<ul style="list-style-type: none"> Angelia presented a handout to the committee reflecting an overview of the types of review processes that are being carried out within the Office of Research Compliance (ORC). There are two types of review processes that are carried out, which are the expedited review process and the full committee review process. The expedited review process allows for electronic review and commenting of the uploaded applications within the IGPS system. Procedures are currently in effect that require certain types of rDNA protocols to be reviewed and approved at a convened meeting. The ORC will continue to upload the applications onto IGPS and notify the committee for review prior to the meeting. Any comments made by committee members are then sent back to the Principal Investigator in a form of a Pending Approval Memo for correction by the PI. After the requested information has been sent back from the PI a review will be assigned to the application. A primary reviewer/presenter will be contacted by the ORC and will be assigned a protocol to review to present the application to the committee at the next convened meeting. The presentation should include the overview of the study, discuss any concerns and comments, and include any recommendations for approval (i.e. approved, request for changes to be made, or a complete disapproval). If a committee member has a conflict of interest on any protocols that are to be voted upon, the committee member will be asked to be excluded from the vote on 	

	<p>the protocol. The member will be allowed to remain in the room during discussion, but will be excluded from the actual vote on the protocol.</p> <ul style="list-style-type: none"> • Angelia reported that the IBC meetings are open to investigators to present their information to the committee and will be placed on the agenda. 	
<p>rDNA Protocols to be Approved</p> <p><u>2005051-Eitan</u></p>	<ul style="list-style-type: none"> • Dr. Wilson gave the committee an overview of Dr. Eitan's reasons for requesting presentation. Dr. Eitan would like to get her work approved under BSL 1 facility specifications opposed to all of her work being conducted in a BSL2 facility. The committee was presented with the question of all work being required to be conducted solely in BSL2 facilities. • Dr. Eitan attended the meeting to present the details of her application to the committee. Dr. Eitan stated that the Lentiviral vectors will be produced and tested in a BSL2 lab. She also stated that the Lentivirus is to be stored in a locked container and marked appropriately inside the BSL1. Dr. Eitan proposed performing the injections in a BSL1 lab, but using extra precautions, such as disinfecting the room at the end of each procedure and only allowing access into the lab by only staff directly involved in the various procedures. • Dr. Eitan also proposed treating waste from the procedures the experiments conducted under BSL1 specifications as BSL2 waste. She stated that moving to a BSL2 laboratory would not be favorable in her department. • The committee discussed the laboratory options that are available to Dr. Eitan to perform her procedures. It was suggested to refer Dr. Eitan to the BMBL for direction of the BioSafety Level requirements that are needed for her procedure. 	<ul style="list-style-type: none"> ▪ It was recommended to have Dr. Eitan upgrade to a BSL2 facility. It was suggested to have Dr. Eitan contact the Environmental Health and Safety for them to come to the laboratory and give detailed information on upgrade to a BSL2 lab. ▪ The motion to accept the application pending the laboratory upgrade was motioned by Dr. Ficht and seconded by Victor Pantusa. The motion was accepted unanimously.
<p><u>2005055-Kao</u></p>	<ul style="list-style-type: none"> • Dr. Ficht presented details of Dr. Kao's new application to the committee. In section VI, Use of Recombinant DNA, the investigator proposed the use of human fibroblasts; however, the Attachment B, Use of Human Subjects, was not included in the application. No description of the use of the fibroblasts was provided either. The committee discussed whether all rDNA applications should be conducted at BSL2 instead of BSL1. 	<ul style="list-style-type: none"> ▪ The recommendation by the committee was for this application to be approved in pending status [1]. ▪ The motion to accept the application pending the submittal of Attachment B was motioned by Angelia and seconded by Rabbi Tarlow. The motion was accepted unanimously. <ul style="list-style-type: none"> [1] Pending status is referred when there are minor changes to the application. During this process the requested changes will be forwarded to the PI to be resubmitted. Once the PI has submitted the corrections the application will be uploaded unto IGPS for the chairs response. If the chairs are satisfied with the changes then an approval letter will be drafted.

<u>2005056-Tizard</u>	<ul style="list-style-type: none"> • Dr. Ficht presented the details for Dr. Tizard's new applicatio. There were three objectives proposed in the application; 1)To explore the nasal vaccine in mice, rats, and ferrets, 2) Usage of Mycobaterium avium and Mycobacterium genavense, which causes disease in birds; and 3) To use plant-based subunit vaccines that will be using viral proteins from different viruses. • The protocol will consist of using plants, rDNA, and animals. The committee expressed a few questions to the PI regarding the protocol, which have already been addressed by the PI. The questions included the housing of the birds and also the concern with using avium bacteria and the influenza viruses in the same lab. Dr. Ficht reported that the response was that the procedures for each media will be done in a separate location by separate personnel. Dr. Ficht stated that everything that is within the guidelines. • Dr. Browder presented the question if the information of the application would be copied to the animal care staff. Angelia replied that the office will maintain a close working relationship in being sure that certain questions were answered. 	<ul style="list-style-type: none"> ▪ The motion to accept the application as submitted was motioned by Dr. Ficht and seconded by Brent. The motion was accepted unanimously. ▪ Brent motioned to amend the previous motion to accept the application contingent on the PI providing assurance that the lab would autoclave left over feed. The motion was accepted unanimously.
<u>2003158-03-Adams</u>	<ul style="list-style-type: none"> • Dr. Ficht presented the details of Dr. Adams' Amendment to the committee. Dr. Ficht stated that the only change for the Amendment would be to add <i>Brucella melitensis</i> experiments in the laboratory. Dr. Ficht stated that the PI has already been approved by the CDC. 	<ul style="list-style-type: none"> ▪ The motion to accept the amendment as submitted was motioned by Dr. Ficht and seconded by Dr. Tarlow. The motion was accepted unanimously.
<u>2004046-03-Chapkin</u>	<ul style="list-style-type: none"> • Dr. Wilson presented the details of Dr. Chapkin's Amendment to the committee. The Amendment was submitted to add additional transgenic mice to the protocol that will be obtained via a commercial source. • There was discussion on how the disposal information is obtained by the ORC to be sure that the mice are disposed of properly. 	<ul style="list-style-type: none"> ▪ The motion to accept the amendment as submitted was motioned by Dr. Wilson and seconded by Dr. Browder. The motion was accepted unanimously.
<u>2004050-01-Liwang</u>	<ul style="list-style-type: none"> • Dr. Wilson presented the details of Dr. Liwang's Amendment to the committee. Dr. Wilson stated that the only change in the protocol is that Dr. Liwang would like to add an additional vector. There was no further discussion regarding the Amendment. 	<ul style="list-style-type: none"> ▪ The motion to accept the amendment as submitted was motioned by Dr. Wilson. The motion was accepted unanimously.
<u>2006003-Wood</u>	<ul style="list-style-type: none"> • Dr. Wilson presented the details of Dr. Wood's application. Because the PI was using E. coli the application was considered an exempt application. 	<ul style="list-style-type: none"> ▪ The motion to accept the application as submitted was motioned by Dr. Wilson and seconded by Dr. Tarlow. The motion was accepted unanimously.
<u>2006004-Ficht</u>	<ul style="list-style-type: none"> • Dr. Ficht presented the details of Dr. Allison Ficht's application. The application contains the use of <i>Mycobacterium avium</i> and <i>Babesia bovis</i>. 	<ul style="list-style-type: none"> ▪ The motion to accept the application as submitted was motioned by Dr. Tarlow and seconded by Dr.

	<p>The majority of the work will be completed under BSL 2 procedures. Dr. Ficht stated that Dr. Allison Ficht had been working without IBC approval for 3 years, without the knowledge that her protocol was expired. Dr. Allison Ficht was approved in the year 2002 under the old IBC process; however, she had not been notified when the new IBC process took place requiring re-approval.</p> <ul style="list-style-type: none"> • Angelia reported that Dr. A. Ficht requested that the committee 1) allow her to continue with her research and 2) allow her to use the data that she has already obtained during the time period in which she did not have IBC approval. 	<p>Browder.</p> <ul style="list-style-type: none"> • The motion was accepted with an abstention by Dr. Ficht, due to a conflict of interest.
Protocol Report	<ul style="list-style-type: none"> • A report reflecting the protocol actions that took place between meetings was provided to the committee members. 	
<p>Old Business</p> <p>a. CDC update – Inspection Process Status</p> <p>b. PI Policy</p>	<ul style="list-style-type: none"> • Angelia reported that to date, there had not been an update on the rescheduling of the inspection CDC. • Brent stated that he had not received any correspondence on standing items that he submitted to CDC a few months ago. Angelia stated that the ORC office will follow up on the standing items. • Tiffany reported that allowing Co-PI's to be on protocols is still an issue that the Office of Research Compliance is working on correcting. According to NIH guidelines, there are clear definitions for PI and Co-Investigators not Co-PI. Angelia reported that the Office of Research Compliance is working on definitions. 	
<p>New Business</p> <p>a. Revised Animal Attachment</p>	<ul style="list-style-type: none"> • Dr. Browder presented the corrected Animal Attachment to the committee. The primary changes in the attachment are changes regarding disposal, autoclave testing and animal disposition upon termination of the project. 	<ul style="list-style-type: none"> • Dr. Browder will be following up with further information for the Committee. The formal presentation will be at a later date.
<p>Date of Next Meeting – Van Wilson</p> <p>a. Meeting Calendar</p>	<ul style="list-style-type: none"> • Next Meeting Date: February 22, 2006 	<p>*The meeting date was rescheduled to February 28, 2006 due to the CDC inspections.</p> <p>*Meeting was later re-scheduled to take place on February 28, 2006, due to the CDC Inspection.</p>
ADJOURNMENT	The meeting was adjourned at 12:52 p.m.	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**APRIL 26, 2006****MINUTES**

MEMBERS PRESENT	VPR STAFF PRESENT	MEMBERS NOT PRESENT	GUESTS
Betsy Browder Jan Faber (non-voting) Tom Ficht Mark Hurt (non-voting) Patricia Klein Victor Pantusa Angelia Raines Jon Skare Frank Stein Vernon Tesh Van Wilson	Tiffany Agnew	Jan Jackson Sara Jordan (non-voting) Jim Joyce (non-voting) Jimmy Keeton Brent Mattox Tim Phillips Rabbi Peter Tarlow	

CALL TO ORDER	The meeting of the Institutional Biosafety Committee was called to order at 11:47 a.m. by Dr. Wilson with 9 voting members present.
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AGENDA ITEM	DISCUSSION/ ISSUES RAISED	RECOMMENDATIONS/ACTIONS/FOLLOW-UP
Introductory Comments – Van Wilson	<ul style="list-style-type: none"> Dr. Wilson mentioned that this meeting would be his last meeting serving as Co-Chair for the IBC. Dr. Wilson additionally thanked each member of the committee for their hard work throughout his term as co-chair. 	<ul style="list-style-type: none"> Angelia moved to approve the minutes as written. Dr. Tesh seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.
rDNA Protocols <u>2004008-Collisson</u>	<ul style="list-style-type: none"> Dr. Ficht presented the details of Dr. Ellen Collisson's submitted amendment. Dr. Ficht mentioned the only issue with the amendment was that he did not find a section in the amendment that described the use of Pathogens. Dr. Ficht suggested that the PI should complete a revision to Section V "Use of Pathogens. Tiffany mentioned that according to the comments provided in IGPS by the Chairs, the information that was submitted on the amendment was sufficient. Dr. Wilson suggested that we ask that each PI include the concentration of the Pathogen. Tiffany stated that once an amendment has been approved, the information will be included within the original 	<ul style="list-style-type: none"> Dr. Wilson moved to approve the amendment pending the completion of Section V in the IBC application. Dr. Tesh seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.

<p><u>2004072-Westhusin</u></p>	<p>protocol as a condensed document.</p> <ul style="list-style-type: none"> • Dr. Wilson presented the details of Dr. Westhusin's amendment. The PI proposed to: 1) add two new BSL2 Rooms to the original protocol; 2) the additional use of alternative versions of the Lentiviral vectors that are currently approved within his protocol; 3) the ability to add additional cell types; and 4) would like to include the use of the private, commercial company Global Genetics and Biological to house the genetically altered animal at this facility. • Angelia requested that the Office of Research Compliance be provided with an IBC approval from Global Genetics to ensure that the work being completed at the facility is covered by a Biosafety Committee. • Approval of off site laboratories that request approval from the Texas A&M IBC can be granted if a letter from an accredited Biosafety Committee has been submitted to the Office of Research Compliance. • Dr. Klein mentioned that the PI was requesting to produce transgenic animals. In referring to Part VI "Use of Recombinant DNA", section III.A, Dr. Klein stated that the question in the application is not clear as to whether the PI will be using a non-commercial source or if genetic alterations will be performed. Dr. Klein suggested separating the question into two separate parts. She also mentioned that the information provided in amendment indicates that the PI would be performing genetically alterations; however, it was not clear. • Dr. Browder raised the question if genetically altered mice were treated different then genetically altered Ag animals. • Dr. Wilson stated that Dr. Westhusin was previously approved at a BSL1; however, the committee will revisit the issue of Lentiviruses and if they are required to be performed under BSL2 conditions. 	<ul style="list-style-type: none"> • Dr. Wilson moved to table the amendment for further discussion.
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<p><u>2004076-Magill</u></p>	<ul style="list-style-type: none"> • The committee requested that the PI clarify if transgenic animals are purchased or if he would be performing the genetic alterations in his laboratory. If no alterations are being performed at the facility, the PI does not need to submit any further information to the IBC. If genetic alterations are being performed at the facility then the PI must include the performance and disposal information for the procedures. • Dr. Wilson presented the details of Dr. Magill's Annual Review. Dr. Wilson stated that his protocol is active and has no changes. There was no additional discussion. 	<ul style="list-style-type: none"> ▪ Dr. Klein moved to approve the annual review as written. Dr. Browder seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.
<p><u>2005028-Mwangi</u></p>	<ul style="list-style-type: none"> • Dr. Ficht presented the details for the amendment submitted by Dr. Mwangi. There was minor discussion on whether the protocol should be approved under BSL1 or BSL2 conditions. 	<ul style="list-style-type: none"> ▪ Dr. Klein moved to approve the amendment under BSL 2 conditions. Dr. Ficht seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.
<p><u>2005043-Alpini</u></p>	<ul style="list-style-type: none"> • Dr. Ficht presented the details of the new application submitted by Dr. Alpini. Dr. Klein mentioned that the PI should include Autoclave procedures. • Tiffany raised the question to the committee if they want to see a full application that incorporates the proposed changes or if the committee only requires the revised section that encompasses the requested changes. • The committee requested that the Office of Research Compliance send the PI correspondence attaching a current version of the IBC application and ask the PI to update his information to include autoclave procedures as requested on the application. 	<ul style="list-style-type: none"> ▪ Dr. Klein moved to approve contingent upon the completion of the autoclave section of the IBC application. Dr. Ficht seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.
<p><u>2005054-Zhang</u></p>	<ul style="list-style-type: none"> • Dr. Wilson presented the details of the new application submitted by Dr. Dekai Zhang. Initially, Dr. Wilson began discussing the particulars of Dr. Cuihua Zhang's application to use transgenic mice that needed to be 	<ul style="list-style-type: none"> ▪ Dr. Wilson moved to approve the application pending additional clarification of Human Cell Culture usage at a Biosafety Level 2. Dr. Klein seconded the motion. There

	<p>reviewed. Dr. Browder also made comments based upon information submitted by the PI. Tiffany made it clear that this was a different "Zhang" than the one of the agenda, and review of this particular protocol began.</p> <ul style="list-style-type: none"> • This protocol involved the use of Pathogens and rDNA, and the use of animals and human and/or human materials. After various revisions to the application, Dr. Wilson indicated that the latest revisions seemed to capture all that was needed, except the clarification of the human cell culture usage. • Victor Pantusa stated that room locations at IBT are in the process of changing due to renovations. Angelia requested that Victor send the IBC confirmation when rooms have changed to cover all protocols that have previously been approved. • Dr. Klein stated that the PI should specify his research objectives in Part I of the application. Dr. Wilson also suggested correspondence with the PI requesting clarification on why Section III.E on the Human Subjects attachment was completed. • Dr. Klein suggested that under Section III.E on the Human Subjects attachment; provide a box for an explanation of the risk posed and how it would be management. 	<p>was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.</p>
<u>2006002-Binas</u>	<ul style="list-style-type: none"> • Dr. Ficht presented the details of the new application submitted by Dr. Bert Binas. Dr. Klein mentioned that the PI should include transportation procedures within the application. • Dr. Browder stated that she will bring the draft of the revised animal attachment that will be included in the IBC application. 	<ul style="list-style-type: none"> ▪ Dr. Wilson moved to approve the application as written at BSL 2 containment. Dr. Klein seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.
<u>2006005-Wantanabe</u>	<ul style="list-style-type: none"> • Dr. Wilson presented the details of the application as submitted by Dr. Coran Wantanabe. The application was not submitted on a current IBC application. The committee decided to request that the PI submit an updated application 	<ul style="list-style-type: none"> ▪ The Committee agreed to table discussion over this protocol until a more current application had been submitted.

<p><u>2006008-Walzem</u></p>	<ul style="list-style-type: none"> • Dr. Wilson presented the details of the new application as submitted by Dr. Rosemary Walzem. There was general discussion on the IBC application. 	<ul style="list-style-type: none"> ▪ Dr. Browder moved to approve the application as written at BSL2 containment. Dr. Wilson seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.
<p><u>2006009-Griffith</u></p>	<ul style="list-style-type: none"> • Dr. Wilson presented the details of the new application as submitted by Dr. Griffith. Some cloning will be involved in the research protocol. Dr. Klein stated that the PI did not provide assurance that the recommended autoclave method will be used. The PI must also specify the use of bleach as decontamination as well if transportation will be used. 	<ul style="list-style-type: none"> ▪ The committee came to a consensus that this protocol would be noted as Pending, upon the PI providing clarification about disposal methods. They also requested that the BSO clarify the use of only 10% of bleach and if bleach was the sufficient decontaminate.
<p><u>2006010-Gentry</u></p>	<ul style="list-style-type: none"> • Dr. Ficht presented the details of the new application as submitted by Dr. Terry Gentry. The PI proposes to work with E. coli TOP 10F pr E. coli JM109. The committee noted that everything was clear; however, they wanted to ensure the PI understood shipping requirements. Tiffany stated that the ORC would send notification to the PI, reiterating shipping requirements. 	<ul style="list-style-type: none"> ▪ Victor Pantusa moved to approve the application at BSL1 containment. Dr. Klein seconded the motion. There was no further discussion. Motion passed with 9 ayes, 0 nays, and 0 abstentions.
<p>Old Business a. CDC update – Inspection Completed</p>	<ul style="list-style-type: none"> • Angelia gave the committee an overview of the response from the CDC inspections. Minor changes were still required. • Angelia stated that she has been working with CDC and is preparing policies and guidelines that will be available to assist PIs, such as adding, changing, and removing personnel from registration. 	
<p>New Business a. Lentiviral Vectors Reviewer Considerations b. rDNA Lab Inspection Schedule</p>	<ul style="list-style-type: none"> • Dr. Wilson gave the committee a general overview and background on Lentiviruses. Dr. Wilson stated that after researching policies regarding the use of Lentiviruses at other institutions, he noted that none of the institutions allows lentiviruses work to be completed under BSL1 conditions. • Brent was not in attendance present the specific details of the rDNA lab inspection schedule. The item has been tabled until the next IBC meeting. The ORC is in the process 	<ul style="list-style-type: none"> ▪ Dr. Wilson proposed that the IBC draft an institutional policy that clearly states the guidelines of lentiviral research.

c. Farewell to Dr. Wilson	<p>of establishing Standard Operating Procedures for the inspections and will discuss the details at the next IBC meeting.</p> <ul style="list-style-type: none"> • The Institutional Biosafety Committee presented an appreciation gift to Dr. Van Wilson for his years of service as a chair of the IBC. Dr. Wilson will remain on the committee as an ex-officio member. • Angelia announced that the Vice President for Research Office will also provide an appreciation lunch honoring Dr. Wilson within the next month. Angelia stated that she will forward the details of the lunch when available. 	
Date of Next Meeting a. Meeting Calendar	<ul style="list-style-type: none"> • Next Meeting Date: May 24, 2006 	
ADJOURNMENT	The meeting was adjourned at 2:21 p.m.	