The University of Oklahoma
Health Sciences Center
OFFICE OF COMPLIANCE

May 17, 2006

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

Dear Mr. Hammond,

Pursuant to your request, we are attaching copies of the approved minutes for University of Oklahoma Health Sciences Center Institutional Biosafety Committee from May 1, 2003 through the date of your request.

We have made minimal redactions to protect either confidential and proprietary information or institutional security.

Sincerely,

Debra L. Chionopoulos

Debra L. Chionopoulos
Director of Compliance and
University Privacy Official

Cc: Joseph J. Ferretti, PhD, Senior Vice President and Provost
Joseph Harroz, Vice President and General Counsel
Cheri Marcham, PhD, Environmental Health & Safety Officer
Dr. Leon Unger, PhD, Chair-OUHSC Institutional Biosafety Committee

Enclosures

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE:	May 27, 2003
TIME:	2:00 p.m.
LOCATION:	BMSB 932
MEMBERS PRESENT:	Leon Unger, Ph.D, Chair Doris Benbrook, Ph.D, Vice Chair Dan Carr, Ph.D. Chris Li, Ph.D. Thomas Kupiec, Ph.D Cheryl Marcham, CIH, CSP, CHMM
MEMBERS ABSENT:	Keeta Gilmore, Ph.D.
GUEST ATTENDEES:	Debra Chionopoulos, Director of Compliance
CALL TO ORDER:	Dr. Unger called the meeting to order at 2:07 p.m.
APPROVAL OF MINUTES:	The minutes of the April 29, 2003 meeting were approved after adding a statement reflecting the discussion of animals used in Protocol #MU/BT 1480 are to be euthanized immediately.
PROTOCOL APPROVAL:	
BT 1493	Dr. Carr moved to approve on condition that documentation of training is provided, Dr. Kupiec seconded the motion. Committee approved.
BT 1494	Dr. Li moved to approve on condition that documentation of training is provided, Dr. Kupiec seconded the motion. Committee approved.
RD/MU 1501	Dr. Kupiec moved to approve on condition that documentation of training is provided and information on whether the vector is obtained commercially, and if so, from where. Dr. Li seconded the motion. Committee approved.
HP 1496	Committee discussed the process of inviting ad hoc committee members for review of this protocol.
HP 1497	Committee discussed the process of inviting ad hoc committee members for review of this protocol.
HP 1503	Committee discussed the process of inviting ad hoc committee members for review of this protocol.
NEW BUSINESS:	Committee discussed the BSL2 security issues, specifically unsecured freezers. According to Debra Chionopolous, the Provost's office supports the security of these freezers. Cheri Marcham will do a campus walk to check the freezers and make a recommendation regarding the new building design. Committee also discussed concerns regarding retroviral vectors that express oncogenes. Dr. Benbrook will do some research and check with NIH guidelines and discuss this issue further next meeting.
ADJOURNMENT:	There being no further business, the meeting was adjourned at 3:10 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: July 30, 2003

TIME: 11:00 a.m.

LOCATION: LIB 223

MEMBERS PRESENT:
Leon Unger, Ph.D., Chair
Keeta Gilmore, Ph.D.
Dan Carr, Ph.D.
Chris Li, Ph.D.
Thomas Kupiec, Ph.D.
Cheryl Marcham, CIH, CSP, CHMM

MEMBERS ABSENT: Doris Benbrook, Ph.D., Vice Chair

ADDITIONAL ATTENDEES: Debra Chionopoulos, Director of Compliance

ADHOC COMMITTEE MEMBERS:
Karen Beckman, M.D.
Eugene Patterson, Ph.D.
James Chodosh, M.D.
Jordan Metcalf, M.D.
Joseph Waner, Ph.D.

CALL TO ORDER: Dr. Unger called the meeting to order at 11:15 a.m.

APPROVAL OF MINUTES: The minutes of the May 27, 2003 meeting were approved.

PROTOCOL APPROVAL:

HP 1496,

Description: A novel Main candidates are those who have ischemia that are in danger of losing their leg and are not candidates for standard traditional therapy such as surgery or medication.

Discussion: Committee discussed the objectives and rationale along with the risks and side effects of the protocol.

Objectives - What is the drug? How does the drug work and how will it help?

The drug is a protein that . The drug is

Rationale - Why was this disease chosen and how will the therapy help if it is effective?

These patients have intermittent claudication and are at a high risk for limb amputation. With treatment there is a chance of preventing limb amputation and improving their quality of life.

Risks and Side Effects - What are the potential adverse reactions? Is there dissemenation of the drug?

None of the adverse reactions were severe, some were unrelated to the drug therapy. Only few mild to moderate reactions were related. There is the potential for dissemenation in some concentration to various locations. There

may or may not be transfection of those sites. Committee agrees that the screening process for colon cancer is sufficient.

Consent Form - The following adjustments should be made.

Line 129 - The risk/possibility of blindness description was too vague. Additional information should be provided including, if possible, the expected frequency of occurrence. The participants should know that there is the potentional for accelerating the process of blindness for those with proliferative eye problems including retinopathy especially in those diagnosed with diabetes, and other undiagnosed eye diseases. The description should include "blindness due to bleeding of blood vessels in the eye".

Line 260 - A comma needs to be inserted after the words "important new information becomes known."

Line 272 - The words "no matter what the cause" should be inserted after the words, "In the event of your death."

A statement is needed in the risk section stating that there may be unforeseeable risks. The consent form for 1497 uses the wording, "Since this is an experimental study and HGF Plasmid has been administered previously to only a small number of humans, participation in this study may involve discomforts or risks to you that are currently unknown or unforeseeable. The statement for 1496 needs to be modified accordingly.

Committee Concerns - The screening process for participants will detect persons with antinuclear antibodies. If antibodies are found what will be done with those participants? The screening process will also detect those who are on coumaden or similar anticoagulant drugs (other than aspirin). What will be done with those people who can not be taken off such medication for an appropriate short time prior to injections?

Overview: After reviewing the given information the committee members stated that there is a considerable chance of death before treatment in the participants so the potential benefits of the proposed treatment weighed in favor of the potential risks, provided that the participants were made aware of the risks.

Approval: Dr. Chodosh moved to approved contingent on the concerns above being addressed, Dr. Waner seconded the motion. Committee approved.

HP 1497,

Description: A Phase II dose ranging study much like 1496, but participants are more severe and unable to walk.

Discussion: Committee discussed the objectives and rationale along with the risks and side effects of the protocol

Objectives - What is the drug? How does the drug work and how will it help?

The drug has

Rationale - Why was this disease chosen and how will the therapy help if it is effective?

These patients are seriously ill, have , are at a very high risk for .

This therapy is intended to

Risks and Side Effects - What are the potential adverse reactions?

Adverse reactions were classified as mild, although this drug has an increased chance of cancer growth compared to 1496.

Consent Form - The following adjustments should be made.

Line 159 - The sentence should be changed to read "If you decide to leave the study early, the study staff will ask you to still undergo the 6 month and 12 month follow-up visits."

Line 171-174 - After the word "address", add "and/or phone number".

Line 349 - The sentence which begins "At certain times during the treatment, it may be dangerous for you to withdraw..." should be removed and replaced with "Withdrawal from follow-up may present a risk to you because we will be unable to monitor you for possible late effects of the drug."

Line 371 - After the words; "...new information becomes available about the drug that is being studied." the words "which may affect your willingness to participate." should be added.

Line 388 - After the words, "In the event of death," the words, "no matter what the cause," should be added.

Committee Concerns - Will patients be screened for antinuclear antibodies? If so, what will be done with those patients with positive results? What actions will be taken based on the results of the prothrombin time (PT), partial thomboplastin time (PTT) and international normalized ratio (INR) tests on these patients.

Overview: After reviewing the given information the committee members stated that there is a considerable chance of death before treatment in the participants so the potential benefits of the proposed treatment weighed in favor of the potential risks, provided that the participants were made aware of the risks.

Approval: Dr. Carr moved to approved contingent on the concerns above being addressed, Dr. Waner seconded the motion. Committee approved.

HP 1503 Committee reviewed the protocol finding that the information provided was insufficient. There are possible safety concerns as well as ethical and legal issues. A subcommittee was formed to further review this protocol comprised of Jordan Metcalf, chair, Eugene Patterson, James Chodosh, Joseph Waner, and Dan Carr.

NEW BUSINESS: The meeting was interrupted early and will be continued on a later date. There was no new business discussed at this meeting.

ADJOURNMENT: There being no further business, the meeting was adjourned at 3:10 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE:	August 7, 2003
TIME:	11:00 a.m.
LOCATION:	BMSB 932
MEMBERS PRESENT:	Leon Unger, Ph.D, Chair Doris Benbrook, Ph.D, Vice Chair Dan Carr, Ph.D. Chris Li, Ph.D. Keeta Gilmore, Ph.D. Cheryl Marcham, CIH, CSP, CHMM
MEMBERS ABSENT:	Thomas Kupiec, Ph.D.
CALL TO ORDER:	Dr. Unger called the meeting to order at 11:15 a.m.
APPROVAL OF MINUTES:	The minutes of the July 30, 2003 meeting were not available for review during this meeting as this is an overlap of that meeting.
PROTOCOL APPROVAL:	
RD/MU 1509	Dr. Benbrook moved to approve on condition that documentation of training is provided and a lab inspection is performed. Dr. Gilmore seconded the motion. Committee approved.
RD/MU 1510	Dr. Benbrook moved to approve on condition that documentation of training is provided and a lab inspection is performed. Dr. Gilmore seconded the motion. Committee approved.
RD/MU 1505	Does not require full committee review, was reviewed and approved by Dr. Unger.
MU 1511	Dr. Benbrook moved to approve on the condition that documentation of DOT training is provided, Dr. Li seconded the motion. Committee approved.
RD/MU 1507	Committee had previously performed an expedited approval by email for this protocol.
NEW BUSINESS:	Committee discussed the memo(s) to be sent to the principal investigator for protocols #1496 and 1497 that would address the issues that were present during the July 7 meeting. Committee also discussed protocol #1503 in that the subcommittee needs a response to Appendix M along with other safety issues and that there should be a deadline set for the information requested.
ADJOURNMENT:	There being no further business, the meeting was adjourned at 1:26 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: September 30, 2003

TIME: 2:00 p.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Leon Unger, Ph.D, Chair
Dan Carr, Ph.D.
Chris Li, Ph.D.
Thomas Kupiec, Ph.D.
Cheryl Marcham, CIH, CSP, CHMM

MEMBERS ABSENT: Doris Benbrook, Ph.D, Vice Chair
Keeta Gilmore, Ph.D.

OTHER ATTENDEE(S): Debra Chionopoulos, Director of Compliance

CALL TO ORDER: Dr. Unger called the meeting to order at 2:09 p.m.

APPROVAL OF MINUTES: Since the Committee wanted more time to review the minutes of the July 30, 2003 meeting and *ad hoc* members should review and provide comments, approval of the Minutes of this meeting was tabled. The minutes of the August 7, 2003 minutes were approved.

PROCEDURAL AND REPORTING CHANGES: Debra Chionopoulos and Dr. Unger announced that the IBC will now be reporting to the Office of Compliance rather than the Office of Research Administration (ORA) effective October 15, 2003. ORA will remain responsible for ensuring that, when appropriate, IBC paperwork is filed prior to submission of grant applications and that funds are not released until IBC approval has been obtained. However, acceptance and routing of forms will now occur through Melissa Pinkston, currently in the IACUC office. She will accept and help track IBC application forms, and will send IBC correspondence such as approval letters.

PROTOCOL APPROVAL:

RD/MU 1517 Committee wants to have review the retroviral vector to be used in this protocol to determine whether there are any additional concerns that should be addressed. Question # 29 regarding training is marked 'no' and needs to be clarified with the researcher. Dr. Carr moved to approve pending acceptable information on vector being receive and clarification of the training question. Dr. Kupiec seconded the motion. Committee approved.

RD/MU 1518 Since the Principal Investigator is a new researcher, Committee has requested that Cheri Marcham perform a lab survey to ensure the facility and workpractices meet BSL2 requirements. Question # 29 regarding training is marked 'no' and needs to be clarified with the researcher. Dr. Li moved to approve pending acceptable lab survey results and the training question being addressed. Dr. Kupiec seconded the motion. Committee approved.

RD/MU 1519 Committee wants to have review the retroviral vector to be used in this protocol to determine whether there are any additional concerns that should be addressed. Dr. Kupiec moved to approve pending acceptable information on vector being received. Dr. Li seconded the motion. Committee approved.

CHANGES TO HUMAN

Committee reviewed the changes made to page 3 and approved the form for use.

NEW BUSINESS:

Committee discussed that the Principal Investigator did not respond to the request for additional information for protocol 1503 by the deadline of September 15, 2003. The committee discussed whether the protocol should be inactivated. Dr. Li moved that if nothing is heard from the PI by 5:00 p.m. on October 1, 2003, the protocol should be inactivated. Dr. Carr seconded. The committee agreed.

Committee wants to review whether a policy has already been adopted regarding the time frame for inactivation of a protocol if no response is received, and review what other committee policies are.

Committee discussed the benefits of inviting a retroviral vector expert to join the committee. Dr. Carr will approach see if he is interested.

Cheri Marcham asked for clarification of whether review of protocols involving biological toxins of a plant source is under this Committee;'s charge. The Committee decided that it was.

ADJOURNMENT:

There being no further business, the meeting was adjourned at 3:15 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE:	January 6, 2004
TIME:	2:00 p.m.
LOCATION:	BMSB 932
MEMBERS PRESENT:	Leon Unger, Ph.D, Chair Doris Benbrook, Ph.D, Vice Chair Michael Sakalian, Ph.D Chris Li, Ph.D. Cheryl Marcham, CIH, CSP, CHMM
MEMBERS ABSENT:	Keeta Gilmore, Ph.D. Tom Kupiec, Ph.D
OTHER ATTENDEE(S):	Debra Chionopoulos, Director of Compliance
CALL TO ORDER:	Dr. Unger called the meeting to order at 2:15 p.m.
APPROVAL OF MINUTES:	The minutes of the 7/30/03 meeting were approved by the Committee via email October 16, 2003. The minutes of the 9/30/03 meeting were not approved as the section on "procedural and reporting changes" needed modifications. Revised minutes will be submitted to the committee.
PROTOCOL APPROVAL:	
RD/MU 1524	Requires modifications to secure approval. Committee requested training documentation on lab personnel and clarification on question 15. SOPs on page 2 need revised, taking off the waste hotline information.
MU 1522	Requires modifications to secure approval. Committee requested training documentation on lab personnel, clarification on question 7, and clarification on question 10, as all lab personnel are not listed. Objectives 1 and 2 need to be expressed. Permit for the virus is unclear, if the permit is in another persons name, that person should be listed on the application. Committee would like to know the location(s) where the virus is housed.
RD 1525	Committee reviewed the protocol finding no issues to be addressed. Committee approved.
RD 1526	Committee reviewed the protocol finding no issues to be addressed. Committee approved.
RD 1527	Requires modifications to secure approval. Committee requested information on the PI, as a student should not be listed as the PI, clarification on question 9, and clarification on question 13. Committee would also like to know what packaging cell lines will be used, will this affect the level of risk, and if the vector can infect human cells?
CHANGES TO IBC FORMS:	Modification to the IBC Protocol Review/Approval Form and the Human Protocol Approval Form were approved.

NEW BUSINESS: Committee suggested some changes to be made to the Resubmission Form. Dr. Unger suggested meeting on tracking issues, possibly doing an annual update similar to IRB and IACUC.

ADJOURNMENT: There being no further business, the meeting was adjourned at 4:20 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE:	February 24, 2004
TIME:	2:00 p.m.
LOCATION:	BMSB 932
MEMBERS PRESENT:	Leon Unger, Ph.D, Chair Doris Benbrook, Ph.D, Vice Chair Michael Sakalian, Ph.D. Keeta Gilmore, Ph.D. Tom Kupiec, Ph.D. Chris Li, Ph.D. Cheryl Marcham, Ph.D, CIH, CSP, CHMM
OTHER ATTENDEE(S):	Debra Chionopoulos, Director of Compliance
CALL TO ORDER:	Dr. Unger called the meeting to order at 2:15 p.m.
APPROVAL OF MINUTES:	The minutes of the 9/30/03 meeting were approved by the Committee with two obstentions. The minutes of the 1/6/04 meeting were approved by the Committee with three obstentions.
PROTOCOL APPROVAL:	
RD 1527	Committee requested verification on dates of submission and the inclusion of missing pages. Benbrook moved to approve with acceptable responses to these clarifications. Li seconded the motion. Committee approved.
RD/MU 1529	Committee reviewed the protocol finding no issues to be addressed. Benbrook moved to approve. Li seconded the motion. Committee approved.
RD/MU 1529a	Committee reviewed the protocol finding no issues to be addressed. Benbrook moved to approve. Gilmore seconded the motion. Committee approved.
RD/MU 1530	Question 19 was not answered, should be E. Answer to question 26 needs to indicate that transport will be sealed not just covered. Benbrook moved to approve with acceptable responses to these items. Gilmore seconded the motion. Committee approved.
RD/MU 1532	Question 10 has only the PI listed. If there will be additional personnel hired they need to be included on the form. Vendor SOPs need to be incorporated with the PI's SOPs. Question 25 needs a room number designated. Benbrook moved to approve with acceptable responses to these items. Li seconded the motion. Committee approved.
RD 1534	Person submitting the protocol is not faculty. Committee tabled this protocol and requested the faculty mentor be identified.
RD 1538	Due to time constraints, the Committee was unable to review this protocol.
MU 1541	Due to time constraints, the Committee was unable to review this protocol.

RD/MU 1544	Due to time constraints, the Committee was unable to review this protocol.
RD 1545	Due to time constraints, the Committee was unable to review this protocol.
RD/BT 1548	Due to time constraints, the Committee was unable to review this protocol.
RD/MU 1549	Due to time constraints, the Committee was unable to review this protocol.
RD/MU 1524	This protocol was originally reviewed at the 1-6-04 meeting. Responses provided by the PI were acceptable to the Committee. Kupiec moved to approve. Sakalian seconded the motion. Committee approved.
RD 1527	This protocol was withdrawn by the PI.
MU 1522	This protocol was originally reviewed at the 1-6-04 meeting. Responses provided by the PI were acceptable to the Committee. Protocol was approved via email on 1/20/04.
CHANGES TO IBC FORMS:	Modification to the IBC Protocol Review/Approval Form were approved with the addition of Dates of Funding and Dates of Initiation.
NEW BUSINESS:	Committee discussed sending out an email to all faculty listing meeting dates, cutoff dates and requirement for inclusion of all pages of the most current form. Committee also discussed having a 15 day cutoff prior to the scheduled meeting dates on protocols received. Discussion also ensued regarding possibly proposing to chairs that they be responsible for submittal to IBC before work is initiated for research funded by their department
ADJOURNMENT:	There being no further business, the meeting was adjourned at 4:10 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE:	March 30, 2004
TIME:	2:00 p.m.
LOCATION:	BMSB 932
MEMBERS PRESENT:	Leon Unger, Ph.D, Chair Keeta Gilmore, Ph.D. Tom Kupiec, Ph.D. Chris Li, Ph.D. Cheryl Marcham, Ph.D, CIH, CSP, CHMM
MEMBERS ABSENT:	Doris Benbrook, Ph.D, Vice Chair
CALL TO ORDER:	Dr. Unger called the meeting to order at 2:13 p.m.
APPROVAL OF MINUTES:	Committee reviewed the minutes of the 2/24/04 meeting. Under New Business, the wording "15 day turnaround" needs to be changed to "15 day cutoff prior to the meeting". With these changes Dr. Kupiec moved to approve. Dr. Gilmore seconded the motion. Committee approved.

PROTOCOL APPROVAL:

RD/MU 1544	Committee reviewed the protocol finding no issues to be addressed. Dr. Li moved to approve. Dr. Kupiec seconded the motion. Committee approved.
RD/BT 1548	Committee reviewed the protocol finding no issues to be addressed. Dr. Gilmore moved to approve. Dr. Kupiec seconded the motion. Committee approved.
RD/MU 1549	Requires modification to secure approval. Committee requested training documentation to be provided. Dr. Kupiec moved to approve provided requested information is received. Dr. Gilmore seconded the motion. Committee approved.
RD/MU 1556	Requires modification to secure approval. Committee requested training documentation to be provided. Dr. Gilmore moved to approve provided requested information is received. Dr. Li seconded the motion. Committee approved.
RD/MU 1554	Question 20 needs to be changed to III-E. Dr. Gilmore moved to approved once original signature is obtained. Dr. Li seconded the motion. Committee approved.
BT 1558	Committee reviewed the protocol finding no issues to be addressed. Dr. Gilmore moved to approve, Dr. Kupiec seconded the motion. Committee approved.
RD 1553	The responses in question number 4 and 42 indicate conflicting room numbers. Committee requested confirmation of correct room numbers. Dr. Kupiec moved to approved upon receipt of information requested. Dr. Gilmore seconded the motion. Committee approved.

PREVIOUSLY REVIEWED PROTOCOLS:

RD 1534	PI resubmitted the protocol per Committee's request with mentor information. Responses in question number 4 and 42 indicate conflicting room numbers. Committee requested confirmation of correct room numbers. Dr. Li moved to approved upon receipt of information requested. Dr. Kupiec seconded the motion. Committee approved.

HUMAN GENE THERAPY PROTOCOL REPORTING INFORMATION:

HGT 1496

PI has delegated reporting responsibilities to ~~Valentis~~. To date, documentation of the required report to NIH/OBA has not been received. An email will be sent to the PI to notify him of this. He will be given a deadline of five days from receipt of the email to get this information to the Committee.

HGT1497

PI has delegated reporting responsibilities to AnGes. The requested information has been received and was reviewed by the Committee.

CHANGES TO IBC FORMS:

Modification to the IBC Protocol Review/Approval Form were not approved. Appropriate changes per discussions will be made and a draft will be redistributed to the Committee for review. Modifications to the IBC Resubmission Form were approved. Modifications to the Human Gene Transfer Form will mirror changes made to the IBC Protocol Review/Approval Form and will be redistributed to the Committee for review.

NEW BUSINESS:

Committee discussed that PI's may not use the IBC Resubmission Form if the original protocol is older than 3 years. Dr. Kupiec moved to approve this motion. Dr. Gilmore seconded. Committee agreed.

As discussed in the prior meeting, the Committee would like to implement a deadline on protocols received. Originally a 15 day cutoff was discussed, but this will conflict with IACUC meeting dates, so the Committee agreed to change the cutoff to 11 days prior to our regularly scheduled meetings for receipt of protocols to be reviewed.

Committee also discussed the need for new members, and to possibly ask to suggest a virologist to serve on the Committee. Discussion of freezer requirements will be on the agenda for the next meeting.

ADJOURNMENT:

There being no further business, the meeting was adjourned at 4:15 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: June 8, 2004

TIME: 2:00 p.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Leon Unger, PhD, Chair
Doris Benbrook, PhD, Vice Chair
Keeta Gilmore, PhD
Chris Li, PhD
Cheryl Marcham, PhD, CIH, CSP, CHMM

MEMBERS ABSENT: Tom Kupiec, PhD.

OTHER ATTENDEE(S): Debra Chionopoulos, JD, Director of Compliance

CALL TO ORDER: Dr. Unger called the meeting to order at 2:15 p.m.

APPROVAL OF MINUTES: Dr. Benbrook moved to approved the revised minutes for the 2/24/04 meeting with the correction of a typo, Dr. Li seconded the motion. Committee approved.

Dr. Marcham moved to approve the minutes of the 3/30/04 meeting, Dr. Li seconded the motion. Committee approved.

PROTOCOL APPROVAL:

MU 1563 Requires modification to secure approval. Committee requested more information on the following: What was the nature of the "unexpected results" in the mouse model system? Did the virus change when passaged through the mouse model system, and if so, what were the changes? What mouse model system was used - mice or mice cells? What information is known about the character of this new new subtype? PI needs to ensure that the baboons will be returned to the colony only if no adverse effects are identified. Dr. Benbrook moved to table until the requested information is received, Dr. Gilmore seconded the motion. Committee tabled.

RD 1560 Committee reviewed the protocol finding no issues to be addressed. Dr. Benbrook moved to approve, Dr. Li seconded the motion. Committee approved.

MU 1550 Requires modification to secure approval. Committee requested more information on the following: On question number 1, the academic appointment and department should be identified. On question number 5, the department from which the source of funds will come should be identified. Question number 8 indicates the facility is a BSL-3, but it is not. On question number 10, PI name should be on the list of personnel, with responsibilities and relevant training/experience identified. On question number 26, filter-top cages should be identified rather than standard rodent cages. Question number 29 should be answered 'yes' since we have received documentation of this training. On the Animal BSL-2 SOP form, item number 5. needs clarification on the entry requirements because there are different requirements depending on whether the animal has been recently infected (within 10 days) or not. Subsequent communication from the PI indicated that a BSC would be used during isolation and infection procedures, and this should be indicated on this form. In addition, the committee wants assurance that the BSC to be used is truly a biological safety cabinet and not a laminar flow hood, which will not protect employees from potential exposure. With the absence of the sink required by CDC and NIH for BSL-2 animal work, the committee has concerns that

an antibacterial hand sanitizer may not be effective against Trichinella spiralis. Dr. Li moved to table until the requested information is received, Dr. Benbrook seconded the motion. Committee tabled.

RD/MU 1561 Committee reviewed the protocol finding no issues to be addressed. Dr. Gilmore moved to approve, Dr. Benbrook seconded the motion. Committee approved.

MU/BT 1566 Requires modification to secure approval. Committee requested clarification on why question 31 regarding training was answered 'no.' In addition, the committee wants assurance that should any other Bacillus anthracis strains are to be acquired by this laboratory (other than the Sterne strain or Delta Sterne strain) the OUHSC IBC requests that it be notified prior to the receipt of those strains. Dr. Gilmore moved to approve pending receipt of requested information, Dr. Benbrook seconded the motion. Committee approved.

MU/BT 1567 Requires modification to secure approval. Committee requested clarification on why question 31 regarding training was answered 'no,' and why the cover letter states that recombinant toxins will be used, but the protocol does not address the use of recombinant toxins, only the toxin derived from the supernatant of the Stern strain. In addition, the committee wants assurance that should any other Bacillus anthracis strains are to be acquired by this laboratory (other than the Sterne strain or Delta Sterne strain) the OUHSC IBC requests that it be notified prior to the receipt of those strains. Dr. Benbrook moved to tabled the protocol until the requested information is received, Dr. Gilmore seconded the motion. Committee tabled.

HUMAN GENE THERAPY PROTOCOL REPORTING INFORMATION:

HGT 1496 Received requested information and reviewed notification of adverse event.

NEW BUSINESS: Freezer requirements discussion was postponed to next meeting. Committee would also like to discuss the PI's submission of a CV with their protocols at the next meeting. Dr. Marcham indicated that she was going to work on having the Organism/Virus/Toxin Inventory updated by IT so that an annual update request can be distributed to PIs.

ADJOURNMENT: There being no further business, the meeting was adjourned at 4:30 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: July 27, 2004

TIME: 2:00 p.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Leon Unger, PhD, Chair
Doris Benbrook, PhD, Vice Chair
Tom Kupiec, PhD
Gillian Air, PhD
Cheryl Marcham, PhD, CIH, CSP, CHMM

MEMBERS ABSENT: Chris Li, PhD

CALL TO ORDER: Dr. Unger called the meeting to order at 2:15 p.m.

APPROVAL OF MINUTES: Committee approved the minutes of the June 8, 2004 meeting as written.

PROTOCOL APPROVAL:

RD/MU 1570

Requires modification to secure approval. Committee requested more information on the following: Question 4 - only the annex is identified. the remainder of the form indicates that the project will also be performed in !

If any of the lab work is to be performed in the room that has no door, this protocol will be held pending assurance that the door has been put in place to limit access during work with microorganisms. Question 11 - only the PI and Co-investigator are named. Other personnel working on this project should be identified, or the statement that these employees will be named later indicated. Also, the answers in the column for relevant training/experience should indicate what these years of experience is in. Question 30 - there is a request to attach SOPs addressing the proper disposal of carcasses. Question 31 - requests that documentation be attached to verify training. In the SOPs it is indicated that the transport of infected material will occur in a styrofoam cooler. If the material is to be transported by vehicle, triple packaging as required by the DOT will be required instead. Dr. Benbrook moved to approve pending receipt of acceptable requested information, Dr. Kupiec seconded the motion. Committee approved.

BT 1571

Requires modification to secure approval. Committee requested that the PI be listed on the personnel list (#11). Dr. Kupiec moved to approve pending completion of personnel list, Dr. Air seconded the motion. Committee approved.

RD/MU 1572

This protocol was not reviewed during the meeting. Committee requested that the protocol be submitted on a current form.

MU/BT 1574

Requires modification to secure approval. Committee requested more information on the following: Question 4 - only room identified, however, the remainder of the form indicates that the project will also be performed in room . In the SOPs it is indicated that a "mouth mask" should be used when handling the toxin. Since "what to do if eye contact occurs" is addressed, the "mouth mask" should be replaced with a face shield or surgical mask/eye

protection combination unit to prevent eye contact as well as mouth contact. Also, it is indicated that plastic-ware that contacts toxin alone will be autoclaved. Committee requests that assurance be provided that autoclaving deactivates the toxin. Dr. Benbrook moved to approve pending receipt of requested information, Dr. Air seconded the motion. Committee approved.

PREVIOUSLY REVIEWED PROTOCOL:

MU 1550	There has been no response to date regarding committee concerns. Dr. Marcham had a discussion with the PI about there being no sink in the lab. They are intending to use alcohol in lieu of a sink. Committee wants assurance that alcohol is an appropriate way to kill Trichinella spiralis.
MU 1563	Information requested by committee was received and approved by email.
MU/BT 1567	Information requested by committee was received and approved by email.
MU/BT 1566	Information requested by committee was received and approved by email.

HUMAN PROTOCOL:

1573	Committee did not review this protocol for approval. Selection of *ad hoc* members was discussed and included the need for a clinical immunologist, a basic science immunologist, a clinical virologist, and a statistician. Also, after some review of the protocol, it has come to the committee's attention that the answer to question 18 is no, which will require the submittal of answers to Appendix M excluding M1.

NEW BUSINESS:

Freezer Requirements	Dr. Marcham had received confirmation regarding the installation of card access for the BRC floors 2-4, however this has not yet occurred.
CV Submission	Committee discussed asking for an abbreviated biosketch similar to that submitted with NIH grants to be attached to any protocol with a classification of III-D or above for the PI and Co-Investigator (if there is one).
Biological Inventory Status	The site is not up and working. When IT gets it fixed, it will be brought to campus for updating.
Scheduled Meetings	Committee discussed changing the meeting day from Tuesdays to possibly Wednesdays due to scheduling conflicts.
ADJOURNMENT:	There being no further business, the meeting was adjourned at 3:58 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: August 25, 2004

TIME: 2:00 p.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Leon Unger, PhD, Chair
Doris Benbrook, PhD, Vice Chair
Chris Li, PhD
Gillian Air, PhD
Cheryl Marcham, PhD, CIH, CSP, CHMM

MEMBERS ABSENT: Tom Kupiec, PhD

CALL TO ORDER: Dr. Unger called the meeting to order at 2:10 p.m.

APPROVAL OF MINUTES: Committee approved the minutes of the July 27, 2004 meeting as written.

PROTOCOL APPROVAL:

MU 1577 — Requires the following additional information to secure approval: Will the animals be returned to the colony infected or will they be isolated until no longer infected? Will the animals be able to infect other animals? Committee would also like to make sure that the PI and personnel have current DOT training. Committee tabled until further information is received.

BT 1576 — Committee reviewed the protocol finding no issues to be addressed. Dr. Li moved to approve, Dr. Air seconded the motion. Committee approved.

RD/MU 1572 — Committee would like to have the project dates verified. There being no other issues to be addressed, Dr. Li moved to approve, Dr. Air seconded the motion. Committee approved.

MU/BT 1578 — Committee would like to know how much toxin is being produced and how much of it is in the liquid cultures. Conditional upon receipt of an acceptable response to this issue, Dr. Air moved to approve, Dr. Li seconded the motion. Committee approved.

BT 1579 — Committee reviewed the protocol finding no issues to be addressed. Dr. Benbrook moved to approve, Dr. Li seconded the motion. Committee approved.

PREVIOUSLY REVIEWED PROTOCOL:

MU 1550 — Committee wants greater proof that alcohol kills the Trichinella. PI needs to produce a letter that states the length of time treated with 80 percent alcohol in order to kill the organism and provide evidence that it does kill it. PI needs to sign and date the letter. This protocol is for maintaining the colony only. Any distribution of this organism needs to show IBC approval prior to transfer. Committee tabled until further information is received.

BT 1571 — Acceptable response received, Committee approved.

NEW BUSINESS: There was no new business to discuss.

ADJOURNMENT: There being no further business, the meeting was adjourned at 3:42 p.m.

Respectfully submitted,

Stormie Leaverton
Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: November 3, 2004

TIME: 10:00 a.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Leon Unger, PhD, Chair
Doris Benbrook, PhD, Vice Chair
Chris Li, PhD
Tom Kupiec, PhD
Gillian Air, PhD
Cheryl Marcham, PhD
Debra Chionopoulos, JD

MEMBERS ABSENT: None

CALL TO ORDER: Dr. Unger called the meeting to order at 10:06 a.m.

APPROVAL OF MINUTES: Committee approved the minutes of the August 25, 2004 meeting as written.

PROTOCOL APPROVAL:

MU-1586	Requires preapproval by the Oklahoma State University Biosafety Committee to secure approval from OUHSC IBC. Dr. Kupiec moved to approve pending receipt of approval of the protocol by OSU, Dr. Li seconded the motion. Committee approved.
RD-1585	Committee reviewed protocol 1585 finding no issues to address. Dr. Benbrook moved to approve, Dr. Air seconded the motion. Committee approved.
MU/BT-1582	Committee discussed conditional approval based on lab visit by Dr. Marcham. Dr. Li moved to approve pending reply from lab visit, Dr. Kupiec seconded the motion. Committee approved.
MU/BT-1583	Committee discussed conditional approval based on lab visit by Dr. Marcham. Dr. Kupiec moved to approve pending reply from lab visit, Dr. Air seconded the motion. Committee approved.
MU/BT-1584	Committee discussed conditional approval based on lab visit by Dr. Marcham. clarify under project responsibilities the organism name. Dr. Benbrook moved to approve pending reply from lab visit and project responsibility clarification, Dr. Li seconded the motion. Committee approved.
MU-1589	If any biological/hazardous materials will be transferred to OMRF, Committee will require approval by the OMRF Biosafety Committee to secure approval from OUHSC IBC. Dr. Benbrook moved to approve pending approval from OMRF, Dr. Air seconded the motion. Committee approved.
RD/MU-1591	Committee reviewed protocol 1591 finding no issues to address. Dr. Benbrook moved to approve, Dr. Kupiec seconded the motion. Committee approved.

PREVIOUSLY REVIEWED PROTOCOL:

MU-1550	Committee would like to know if PI has been able to obtain a Biological Safety Cabinet and needs clarification about use of bleach or alcohol and proof of it killing the organism. Committee tabled until further information is received.
RD/MU-1570	Since acceptable response received, protocol met approval requirements.
RD/MU-1572	Since acceptable response received, protocol met approval requirements.
MU-1577	Since acceptable response received, protocol met approval requirements.
MU/BT-1578	Since acceptable response received, protocol met approval requirements.

NEW BUSINESS:

Nanoparticles	Dr. Marcham posed the question, does the Committee need to discuss gene delivery via nanoparticles? The committee agreed yes, such protocols should be reviewed and approved through this Committee.
Transgenics	Dr. Marcham raised an issue identified by IACUC regarding the generation of transgenic mice and frogs as to whether the PI or the facility creating the transgenic should submit the protocol. The committee all agreed that a new form could be created to have both submit and sign.
ADJOURNMENT:	There being no further business, the meeting was adjourned at 11:45 a.m.

Respectfully submitted,

Devon Williams
Temporary Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: November 30, 2004

TIME: 2:00 p.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Leon Unger, PhD, Chair
Doris Benbrook, PhD, Vice Chair
Chris Li, PhD
Tom Kupiec, PhD
Cheryl Marcham, PhD
Debra Chionopoulos, JD

MEMBERS ABSENT: Gillian Air, PhD

CALL TO ORDER: Dr. Unger called the meeting to order at 2:18 p. m.

APPROVAL OF MINUTES: Committee approved the minutes of the November 3, 2004 meeting as written.

PROTOCOL APPROVAL:

1593	Committee discussed approving protocol with a note of caution. The committee is concerned about how long needles will be sitting in sharps containers before they are autoclaved. Dr. Benbrook moved to approve protocol pending acceptable response to concerns about needles, Dr. Kupiec seconded the motion. Committee approved.
MU 1594	Committee would like PI to clarify the following: (1) What is the intended start date for the protocol? (2)The listed co-PI is not on the personnel list. (3) A more thorough explanation of the use of the microorganism is needed. (4) What strain of E.coli will be used? (5) Are the proteins recombinant or will there by any recombinant DNA work done in this protocol? Committee tabled until further information is received.

PREVIOUSLY REVIEWED PROTOCOL:

MU 1550	Committee discussed conditional approval based on finding out the effects of xylol on the skin on a daily basis. Dr. Benbrook moved to approve protocol pending receipt of information on xylol, Dr. Li seconded the motion. Committee approved.
MU 1586	Since acceptable response received, protocol met approval requirements.
MU/BT 1582	Since acceptable response received, protocol met approval requirements.
MU/BT 1583	Since acceptable response received, protocol met approval requirements.
MU/BT 1584	Since acceptable response received, protocol met approval requirements.
MU 1589	Since acceptable response received, protocol met approval requirements.
RD/MU 1572	Since acceptable response received, Committee approval performed via email.

MU 1577	Since acceptable response received, Committee approval performed via email.
MU/BT 1578	Since acceptable response received, Committee approval performed via email.

DRAFT TRANSGENIC FORM: The new proposed form for the creation of transgenic animals was discussed. Some changes were proposed. A revised draft will be brought to the next meeting.

NEW BUSINESS: No new business.

ADJOURNMENT: There being no further business, the meeting was adjourned at 3:24 p.m.

Respectfully submitted,

Devon Williams
Temporary Recording Secretary

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: January 25, 2005

TIME: 2:00 p.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Leon Unger, PhD, Chair
Doris Benbrook, PhD, Vice Chair
Gillian Air, PhD
Tom Kupiec, PhD
Cheryl Marcham, PhD
Debra Chionopoulos, JD

MEMBERS ABSENT: Chris Li, PhD

CALL TO ORDER: Dr. Unger called the meeting to order at 2:20 p.m.

APPROVAL OF MINUTES: Committee approved the minutes of the November 30, 2004 meeting as written.

PROTOCOL APPROVAL:

1605 — Committee discussed concerns that no other laboratory employee was identified on the protocol other than the PI. Committee requested that approval letter state that any employees hired to perform work on this protocol should receive training and the IBC should receive copies of the training prior to the employee performing any work. Dr. Benbrook moved to approve protocol with this condition. Dr. Air seconded the motion. Committee approved.

1532A — Dr. Kupiec moved to approve, Dr. Benbrook seconded, and the Committee approved.

1606 — Dr. Kupiec moved to approve, Dr. Benbrook seconded, and the Committee approved.

1599 — Committee noted that the biosketch for the PI and training for a listed laboratory employee were not included in the protocol submission. Dr. Air moved to approve pending receipt of this information. Dr. Benbrook seconded. Committee approved.

PREVIOUSLY REVIEWED PROTOCOL:

1593 — Since acceptable response received, protocol met approval requirements.

1594 — Committee noted that the biosketch for the PI and Co-investigator were needed. In addition, in the description of the project, it is stated, "We intend to manipulate the protein C system by use of various antibodies..." The committee would like to know whether this implies that recombinant DNA work will be performed. If so, section II of the form should be completed and the recombinant portion of the project described. If not, the PI should state that no recombinant DNA work will be performed. Dr. Benbrook moved that the protocol be approved conditional upon receipt of the biosketches and that the PI states that no recombinant work will be performed. Dr. Air seconded. Committee approved.

Human Protocol for Future Review	Committee was given copies of a human protocol that would be discussed at the next meeting, and apprised that *ad hoc* member(s) would be contacted to assist with the review. Therefore, the next meeting date will be determined and announced as soon as a meeting date can be identified that all regular and *ad hoc* committee members could attend.
Adverse Event Reporting	A listing of adverse events related to Human Protocol 1496 were provided by the PI to the IBC in addition to documentation indicating that protocol was stopped after the interim data analysis showed that the subjects in the placebo arm had as much improvement as those in the treatment arm. Dr. Marcham indicated that she was still attempting to obtain copies of the required reports to NIH for this protocol and 1497.
New Business	
IBC/IRB Responsibilities	Documents outlining the differences in requirements and responsibilities of the IRB and IBC were provided to the Committee for review. Dr. Unger suggested that these not be discussed at this meeting, rather, that this be an issue for future discussion and development.
Transgenic Form	The draft Transgenic Form was presented to the Committee. Additional refinements were suggested.
Transfer of Pathogens Form	A Transfer of Pathogens Form used by another institution was provided to the Committee for review and to discern whether we should create a similar form. Ms. Chionopoulos suggested that Dr. Marcham contact the Technology Transfer representative on campus for additional assistance. It was determined that this issue would be re-addressed at a future meeting.
NIH Report	Committee members were advised that the annual report to NIH would be due soon, and that current information would be needed from each.
ADJOURNMENT:	There being no further business, the meeting was adjourned at 4:00 p.m.

Respectfully submitted,

Cheri Marcham
IBC Member

The University Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE:	February 25, 2005
TIME:	11:00 a.m.
LOCATION:	BMSB 833
MEMBERS PRESENT:	Dr. Leon Unger, Chair Dr. Doris Benbrook, Vice Chair Dr. Gillian Air Dr. Chris Li Debra Chionopoulos Dr. Cheri Marcham Dr. Tom Kupiec Dr. James Chodosh (*ad hoc*)
CALL TO ORDER:	Dr. Benbrook called the meeting to order at 11:38 a.m. and chaired the meeting until Dr. Unger arrived

PROTOCOL APPROVAL:

1610/1611	Dr. Li moved to approve. Dr. Air seconded, and the Committee approved
1612	The Committee discussed concerns about the cardboard box used for transportation and the animals used in the laboratory. Do the boxes have any potential for contamination? If so, do they need to be disinfected between uses? How will the box be disposed? Are the animals killed prior to removal of the tissue? What process is used to kill the animals? Is the process performed in the biological safety cabinet (BSC)? Is the collection of the lavage also performed there? The answer to question 45 was incomplete. Dr. Li moved to approved pending acceptable answers to questions and completion of information provided for question 45. Dr. Air seconded, and the Committee approved.
1613	The Committee found one item to be changed. The protocol listed a BSL3 when the lab is rated only for BSL2.

Dr. Marcham will email the PI with intention to correct and initial the change, and request whether the PI concurs.

Dr. Benbrook moved to approve. Dr. Li seconded, and the Committee approved.

HP 1603

This protocol is entitled, '

"

The Committee discussed several items in regards to this protocol. The first item is the submission of

's biosketch. His project responsibilities and relevant training/experience have not been identified in question number 10 on the protocol application form. Information is needed to complete this question.

In question number 18 on the protocol application form, the answer was submitted as yes. The Committee believes the appropriate answer is "No", since for part "a", the vector encoded immunogen is microbial in origin nor is an immune response to it the major goal. GM-CSF is a human gene product and the major goal is to stimulate an immune response to cellular tumor antigens.

Side effects noted on page 15 of 19 in the document provided which addresses all responses to Appendix M are not noted in the Consent Form. Specifically, ulceration at the injection site, low blood pressure (hypotension), and inflammation (phlebitis) are not in the Consent Form and should be added.

The Committee requests the person administering the drug be a chemotherapy nurse because such nurses are already trained in procedures and hazards of administering toxic substances. The person(s) preparing and administering the drug should be required to know all of the information covered in the Consent Form so that they are made aware of the potential hazards associated with accidental exposure/injection of the drug. A "safe needle device" appropriate for the purpose should be used for administering the drug. These issues must be addressed.

The application package does not identify the location of the pharmacy nor the location where administration will occur. The locations must be identified and a time

arranged for Dr. Marcham to visit the locations. A method of transport of the drug must also be described.

The Committee expressed concerns regarding the disposal of unused or partially used vials of study medication. The protocol simply states that "Any material that come in contact with CG1940 and CG8711 should be disposed of as biohazardous waste (e.g., sharps containers, biohazard bag) according to the institutions SOP's". The facility SOP's for disposal are required. It must also include a statement that the material will be marked for incineration. Just referencing the OUHSC biomedical waste vendor is not sufficient. Unless the container is marked for incineration, it would likely be autoclaved.

Dr. Chodosh moved to approve, Dr. Kupiec and Dr. Air seconded. The Committee approved pending recommended changes accomplished.

PREVIOUSLY REVIEWED PROTOCOLS:

1605	Since acceptable response received, protocol met approval requirements.
1599	Since acceptable response received, protocol met approval requirements.
1594	Since acceptable response received, protocol met approval requirements.

NEW BUSINESS:

Transgenic Form	Changes were suggested and another version will be brought to the next meeting.
Revised Protocol Form	The form is showing the modifications suggested at the last Committee meeting but further changes are still required. Another version will be brought to the next meeting.

ADJOURNMENT: There being no further business, the meeting was adjourned at 2:15 pm.

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE:	March 29, 2005
TIME:	1:30 p.m.
LOCATION:	BMSB 932
MEMBERS PRESENT:	Dr. Leon Unger, Chair Dr. Doris Benbrook, Vice Chair Dr. Gillian Air Dr. Chris Li Dr. Cheri Marcham Dr. Gene Patterson (*ad hoc*) Dr. Karen Beckman (*ad hoc*) Dr. Jordan Metcalf (*ad hoc*) Debra Chionopoulos
MEMBERS ABSENT:	Dr. Tom Kupiec
CALL TO ORDER:	Dr. Unger called the meeting to order at 1:47 p.m.
APPROVAL OF MINUTES:	Committee approved the minutes of the January 25, 2005 minutes as written, which were updated as a result of comments at the last meeting. The February 28, 2005 minutes were approved with the change of the meeting location from the Faculty House to BMSB 833.

NEW PROTOCOL APPROVAL:

1614	The Committee requests that the undergraduate student be removed as a Co-investigator but kept with project responsibilities in item number 11. The Committee requests clarification of the last sentence of item 45, which states, "Furthermore, the retina is an immune privileged tissue, so there is no risk of the transposase affecting other cells outside of the retina." With the understanding that these items will be addressed and clarified with the PI, Dr. Li moved to approve, Dr. Benbrook seconded, and the Committee approved.
1615/1615A	Dr. Marcham advised the Committee that the PI has not responded to her requests to conduct a laboratory safety survey. The Committee tabled the protocol pending an acceptable outcome of a laboratory safety survey.
1616	No concerns were identified. Dr. Benbrook moved to approve the protocol, Dr. Air seconded, and the Committee approved.
1619	No concerns were identified. Dr. Li moved to approve the protocol, Dr. Benbrook seconded, and the Committee approved.
1620	Dr. Marcham reported that she sent requests for additional information to the PI via email and has yet to receive a response. It was also noted that the response to item number 45 did not describe the project with respect to the use of the microorganism. An explanation of how the microorganism will be used is needed. The Committee tabled the protocol until the requested information is received.
1621	The answer to item 16 on the submitted protocol should reflect a method not a person. In item number 21, the Committee requested that the task of

"removing the bladder" be listed, and the PPE listed (to include an N-95 respirator, since a Biological Safety Cabinet is not available for this procedure.) Dr. Benbrook moved to approve the protocol with the appropriate changes, Dr. Marcham seconded and the Committee approved it.

HP 1607

The Committee discussed the risks to the healthcare worker who may accidentally be exposed. The Committee determined that follow up should occur just as if the provider was a patient, including cancer screening. Patients will continue to be seen for two years and will be contacted for fifteen years after the injections take place, and so should anyone occupationally exposed.

Question number 10 on the application form lists only the PI and technicians, whereas several additional investigators are listed on the associated IRB protocol. Questions regarding how they will be involved with this trial and whether they have received or need the appropriate training were raised? Committee determined that these investigators need to be included in the IBC protocol or an explanation is needed of why they are not listed.

Question number 11 of the IBC form requests standard operating procedures (SOPs) developed, signed and dated by the PI indicating procedures for employee training, safety precautions, and handling of patient fluids/excreta. The response provided indicated that Pharmacy Instructions will be sent to the Pharmacist. The response also indicated that body fluid samples will be collected, but no SOP is provided for the safe collection/handling of these fluids. Information regarding whether safe medical devices will or should be used should be included in the SOPs. Appendix M, p. 50, is referenced, but the manual has not been provided to the Committee. On the same page, a statement is made indicating that guidelines for managing inadvertent exposures were in place for Phase 1 and will be in place for this Phase 2, but these guidelines were also not provided. The Committee does not believe this response provides the IBC with the requested SOPs. Therefore, the PI needs to prepare, sign, date, and submit SOPs which address safe procedures for administering and handling the drug and patient specimens, spill response procedures, and procedures for and risks associated with an accidental exposure (it is important that healthcare workers who are accidentally exposed receive immediate and long-term follow-up care to address any potential concerns). These SOPs may include, but need not be limited to, the Pharmacy instructions/manual and the referenced guidelines for managing inadvertent exposures.

Relative to the procedures for employee training, evidence that all affected employees will be trained on these SOPs is needed.

The Committee is in receipt of a copy of correspondence in which the PI transferred all reporting responsibilities per Appendix M-I-C-4 of the NIH Guidelines to Genzyme. Section M-I-C-4 of the Guidelines refers to reporting serious adverse events only. Other reporting requirements are identified in the Guidelines which include submitting (1) a report to the NIH within 20 working days after enrolment of the first research participant; (2) a report to the NIH to add a clinical trial site; and (3) annual reports to NIH.

Although the corporate sponsor and other clinical trial sites for this study may not have to report to NIH, the OUHSC is required to comply with the reporting requirements because we receive funding from NIH. According to the NIH, it becomes the PI's responsibility to file these reports if the sponsor chooses not to do so. The Committee requires confirmation of whether the sponsor has agreed to report this information to NIH or whether

the PI will be reporting this information to NIH. If the PI will be reporting this information to NIH, the reports must be transmitted through the OUHSC IBC office. If the sponsor has agreed to report this information to NIH, the PI must verify that these reports have and will be filed in a timely manner and provide to the IBC written confirmation from the sponsor that these reports have been filed. Committee members noted that if the Sponsor does not agree to comply with these reporting requirements, the trial should not be performed at the OUHSC because we would be in non-compliance with the NIH Guidelines.

Section 9.15.4 of the Clinical Protocol, "Adverse Event and Serious Adverse Event Reporting" (pages 71 and 72) includes requirements for reporting Serious Adverse Events (SAEs) to the sponsor and the Institutional Review Board. It is important for the PI to know that all such SAEs occurring at the OUHSC clinical trial site must also be reported to the OUHSC IBC.

The Committee asked for clarification on the subject of where the drug will be administered and how the drug will be transported to the clinical study site.

The Committee noted that should the IRB recommend changes to the Consent Form, the IBC must review and approve the revised Consent Form. Dr. Marcham issued a reminder that language that was underlined in the provided Consent Form was specifically added to meet IBC requirements.

Dr. Beckman moved for approval and Dr. Benbrook seconded contingent on the submission of acceptable additional information, that the final revised consent form be submitted to the IBC for approval, and the clarification of who will do the reporting to the NIH.

PREVIOUSLY REVIEWED PROTOCOL:

1603	Since acceptable response received, protocol met approval requirements.
1610/161	Since acceptable response received, protocol met approval requirements.
1612	Since acceptable response received, protocol met approval requirements.
1613	Since acceptable response received, protocol met approval requirements.

NEW BUSINESS: Since the only new business needing discussion was review of the proposed Transgenic Form and changes to the Revised Protocol Form, this new business was deferred to the next meeting.

ADJOURNMENT: There being no further business, the meeting was adjourned at 4:22 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: April 26, 2005

TIME: 2:00 p.m.

LOCATION: BMSB 932

MEMBERS PRESENT: Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Chris Li
Dr. Cheri Marcham
Dr. Tom Kupiec

MEMBERS ABSENT: Dr. Gillian Air
Debra Chionopoulos

CALL TO ORDER: Dr. Unger called the meeting to order at 2:08 p.m.

APPROVAL OF MINUTES: The Committee set aside the approval of the March 29, 2005 minutes. Revisions to the minutes are to be made to the last paragraph of the second page. The verbiage is to be changed to read in the present tense. Also, the *ad hoc* members and absent members have yet to review the minutes for their approval.

PREVIOUSLY REVIEWED PROTOCOLS:

HP 1607

The Committee reviewed the supplemental information provided by the PI. An agreement was made to forward a copy of the supplemental information to the *ad hoc* members for their review.

The PI was notified in an email dated 4/1/05 that while the Clinical Protocol for this study includes requirements for reporting Serious Adverse Events (SAEs) to the sponsor and the Institutional Review Board, that all SAEs occurring at the OUHSC clinical trial site must also be reported to the OUHSC IBC. The PI must acknowledge that should an SAE occur at OUHSC, that the OUHSC IBC will be notified.

Information has yet to be received regarding where the drug will be administered, whether transport from the Pharmacy would be required, and if so how the drug would be transported.

1573

It was brought to the Committee's attention that the Investigator Brochure has been revised by removing Appendix I of the brochure.

The Committee asked Dr. Marcham to review correspondence to the PI to determine the status of reporting requirements.

TABLED PROTOCOLS:

1615

Dr. Unger requested that the strain of E. coli be added in item 23. Dr. Marcham added the strain from the information on the attachments and initialed it.

The Committee has concerns regarding number 30. The protocol states animals are being housed in , however, the experiment is to be done in . The PI states that the animals will be taken to the lab prior to the injection being given. If infected animals are not going to be transported, then the question is regarding the amount of time the animals will be held in the lab before being euthanized. The Committee requests that information be obtained from the

IACUC Committee on the maximum time period animals may be kept in the lab.

Dr. Benbrook had some concerns over item 16, which states equipment will be wiped with alcohol. The PI should state what percent of alcohol will be used.

Homogenization of the bladder needs to be added to item 19.

The protocol was approved upon the clarification of these matters. Dr. Li moved to approve with Dr. Benbrook seconding, the Committee approved.

1615A/1615B — The protocols were tabled pending the outcome of the response from #1615.

1620 — This protocol continues to be tabled due to no response from the PI.

NEW PROTOCOL APPROVAL:

1623 — Item 21 of the protocol is to be completed with the information IIID. Dr. Kupiec moved to approve the protocol and Dr. Li seconded.

1624 — The Committee wants to review the overall grant application to see how the specific aims fit together in order to be able to better view the project as a whole.

On item 23, the PI lists "Autographa californica multiple nuclear polyhedrosis virus", but does not discuss it in any of the other parts of the application. The Committee requires clarification from the PI whether the virus should be removed from the protocol or if further information is to be provided. The protocol was tabled pending receipt of the requested information.

1626 — The Committee had questions regarding number 40 of the protocol which questions where the animals will be housed. The PI states . and animal Numbers 4 and 39 ask project location, which the PI states The SOPs, however, state that treated animals will not be returned to the animal facility. Clarification is needed of whether toxin will be taken at any time from the lab to the animal facility. If toxin is not used or taken to the animal facility, nor are treated animals taken to the animal facility, the animal facility should be taken off the project location(if they are just being housed until the PI treats them and are not to be returned.) If the toxin is taken to the animal room, or treated animals are transported, then this should be clarified and the method of transporting either the toxin or the treated animals should be provided to the Committee.

With the understanding that these items are to be clarified, Dr. Kupiec moved to approve the protocol and it is seconded by Dr. Li.

NEW BUSINESS:

Transgenic Form — The transgenic/knockout form was approved as is. Dr. Kupiec moved to approve, with Dr. Li seconding it.

Revised Protocol Form — Additional revisions were recommended.

Human Protocol Form — Additional revisions were recommended.

ADJOURNMENT:

There being no further business, the meeting was adjourned at 4:00 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: June 13, 2005

TIME: 1:30 p.m.

LOCATION: BMSB 833

MEMBERS PRESENT: Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Chris Li
Dr. Cheri Marcham
Dr. Tom Kupiec
Dr. Gillian Air

MEMBERS ABSENT: Debra Chionopoulos

CALL TO ORDER: Dr. Unger called the meeting to order at 1:47 p.m.

APPROVAL OF MINUTES: The Committee reviewed the revisions of the March 29, 2005 minutes. Dr. Benbrook moved to approve the minutes and Dr. Air seconded. The April 26, 2005 minutes were also reviewed. Dr. Li moved to approve the minutes and Dr. Benbrook seconded. The minutes of both meetings were approved by the Committee.

TABLED PROTOCOLS:

1624 Dr. Kupiec moved to approve the protocol contingent on the PI's notification and agreement that his laboratory will maintain a BSL 3 level for all research using the HBRV virus and Dr. Li seconded. The Committee approved.

1620 A response has yet to be received from the PI. Dr. Marcham is to notify ORA that the protocol is tabled until a response is received from the PI.

NEW PROTOCOL APPROVAL:

1628 Dr. Air moved to approve and Dr. Kupiec seconded. The Committee reviewed and approved the protocol.

1630 A copy of the IACUC protocol was requested for further review of the procedures of handling of the infected animals. A copy was received, reviewed and attached to the IBC protocol in order to provide the additional information needed.

Dr. Kupiec moved to approve and Dr. Li seconded. The Committee approved the protocol.

1635 Dr. Li moved to approve the protocol contingent on the clarification from the PI of the procedures of hand washing before leaving the lab. Dr. Air seconded. The Committee approved.

1636 Dr. Li moved to approve the protocol contingent on the clarification from the PI of the procedures of hand washing before leaving the lab. Dr. Air seconded. The

Committee approved.

NEW BUSINESS:

Transgenic Form	Dr. Air moved to approve the transgenic/knockout form with the change of the word "indicate" to "specify" throughout the form. Dr. Li seconded. The Committee approved the form.
Revised Protocol Form	Dr. Li moved to approve the form "as is". Dr. Kupiec seconded. The Committee approved the form.
Human Protocol Form	Dr. Benbrook moved to approve the form with the revision of the wording "If not faculty" replacing "If Post-Doctoral Fellow". Dr. Air seconded. The Committee approved the form with the changes.
Resubmission Protocol Form	Dr. Air moved to approve the form "as is". Dr. Kupiec seconded. The Committee approved the form.

ADJOURNMENT:

There being no further business, the meeting was adjourned at 2:50 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: July 26, 2005

TIME: 2:00

LOCATION: BMSB 932

MEMBERS PRESENT: Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Chris Li
Dr. Cheri Marcham
Debra Chionopoulos
Dr. Gillian Air

MEMBERS ABSENT: Dr. Tom Kupiec

CALL TO ORDER: Dr. Unger called the meeting to order at 2:15 p.m.

APPROVAL OF MINUTES: The Committee reviewed the June 13, 2005 minutes. Dr. Benbrook moved to approve the minutes and Dr. Air seconded. The minutes were approved by the Committee.

NEW PROTOCOL APPROVAL:

1643 The Committee needed clarification of some items. The protocol states that preliminary results are necessary for a grant to be submitted to NIH but does not say who the funding agency is. The SOPs were not complete. Certain items that needed to be circled were not. The Committee had a question of whether or not hydrogen peroxide deactivates LPS and if the BCG is a liquid or a powder. Dr. Li moved to table the protocol and Dr. Benbrook seconded. The Committee tabled the protocol.

1644 Dr. Benbrook moved to approve and Dr. Air seconded. The Committee reviewed and approved the protocol.

HUMAN PROTOCOL:

1573 The Committee noted that the researcher is of the opinion that the adverse event was not related to the use of the gene transfer product. Given the information provided to the Committee, no additional concerns were raised regarding the use of the gene transfer product. Dr. Benbrook moved to approve the Committee's position on the matter. Dr. Air seconded.

ADJOURNMENT: There being no further business, the meeting was adjourned at 3:13 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: August 24, 2005

TIME: 2:00

LOCATION: BMSB 932

MEMBERS PRESENT: Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Chris Li
Dr. Cheri Marcham
Debra Chionopoulos
Dr. Gillian Air
Dr. Tom Kupiec

CALL TO ORDER: Dr. Unger called the meeting to order at 2:06 p.m.

APPROVAL OF MINUTES: Approval of the July 26, 2005 minutes was deferred to the next meeting, as the minutes were not reviewed by all Committee members at the time of the meeting.

NEW PROTOCOL APPROVAL:

1568 This protocol did not require full committee approval. However, it was one of the first protocols to be completed on the new transgenic/knockout form so was submitted for full committee review. The committee approved the protocol.

1649 Dr. Benbrook moved to approve and Dr. Kupiec seconded. The Committee approved the protocol.

1652 This protocol did not require full committee approval. However, it was one of the first protocols to be completed on the new transgenic/knockout form so was submitted for full committee review. The committee approved the protocol.

1653 This protocol did not require full committee approval. However, it was one of the first protocols to be completed on the new transgenic/knockout form so was submitted for full committee review. The committee approved the protocol.

1654) Dr. Kupiec moved to approve and Dr. Benbrook seconded. The Committee approved the protocol.

1657 Dr. Air moved to approve and Dr. Kupiec seconded. The Committee approved the protocol.

1659 As the protocol states training will be done and research will be supervised by an individual in the lab other than the PI, the Committee requested that the individual be listed as a co-investigator with project responsibilities, sign the protocol form and also sign the SOPs. Dr. Benbrook moved to approve the protocol contingent on these changes and Dr. Kupiec seconded. The Committee approved the protocol.

1660 Upon review of the protocol, the Committee requested additional information. In number 11, the additional employee was added to the protocol as requested,

however her project responsibilities and relevant training/experience are needed to complete her information.

The Committee is also unclear as to the genes that will be studied. As the Committee understands the process proposed, *P. aeruginosa* genes will be selected to be cloned into *E. coli* K12. Then the genes of interest will be inserted back into the *P. aeruginosa* and their respective functions will be studied. The Committee needs to know if the genes are modified in any way when put back into the original host. Also, if there is any possibility that this procedure might modify the organism to become more virulent.

Dr. Benbrook moved to table the protocol and Dr. Kupiec seconded. The Committee tabled the protocol pending receipt of the required information.

1661

Upon review of the protocol, the Committee requested additional information. In number 11, the additional employee was added to the protocol as requested, however her project responsibilities and relevant training/experience are needed to complete her information.

The Committee is also unclear as to the genes that will be studied. As the Committee understands the process proposed, P. *aeruginosa* genes will be selected to be cloned into *E. coli* K12. Then the genes of interest will be inserted back into the *P. aeruginosa* and their respective functions will be studied. The Committee needs to know if the genes are modified in any way when put back into the original host. Also, if there is any possibility that this procedure might modify the organism to become more virulent.

Dr. Benbrook moved to table the protocol and Dr. Air seconded. The Committee tabled the protocol pending the receipt of the required information.

1664 (

Upon review of the protocol the Committee required additional information. The title of the proposal was not complete on the protocol. The complete title will have to be provided.

The co-investigator has not signed the protocol. His signature is needed on the protocol.

Additional information regarding the PI's training and experience related to this proposal is needed. The committee is unfamiliar with the term, "densitomerist" she has used to describe her experience. A copy of the PI's biosketch will be requested. Dr. Benbrook moved to approve the protocol contingent on these changes and Dr. Unger's approval of the biosketch. Dr. Kupiec seconded. The Committee approved the protocol.

TABLED PROTOCOLS:

1643

Since acceptable response received, protocol met approval requirements. Dr. Kupiec moved to approve the protocol. Dr. Air seconded.

HUMAN PROTOCOLS:

1573

While the adverse event was first reported as not related to the study, it is now being reported as possibly related to the study but not to the gene transfer product.

1665

Dr. Unger is working to obtain *ad hoc* Committee members to review the protocol.

ADJOURNMENT:

There being no further business, the meeting was adjourned at 3:31p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: September 13, 2005

TIME: 10:00

LOCATION: BMSB 932

MEMBERS PRESENT:
Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Chris Li
Dr. Cheri Marcham
Debra Chionopoulos
Dr. Gillian Air
Dr. James Jarvis*(Ad Hoc)*
Dr. Judy James*(Ad Hoc)*
Dr. William Hildebrand*(Ad Hoc)*

MEMBERS ABSENT: Dr. Tom Kupiec

CALL TO ORDER: Dr. Unger called the meeting to order at 10:09 p.m.

PROTOCOL APPROVAL:

HP 1665

Description:

This protocol is entitled.

It is sponsored by I

The study involves immunizing women who have cervical dyplysia to elicit a reaction against HPV to prevent it from progressing to cancer.

Discussion:

The Committee discussed the concern of the transforming sequences of the genes. The Committee needs additional information from the PI on whether the transforming sequences of E6 and E7 are excluded from the construct. If included, which sequences are included need to be provided to the committee. Also if they are included in an intact manner, clarification of clear evidence that the genes will not transform a normal cell into a cancer cell is required. Dr. James offered to provide the sequences of genes that should be excluded.

Antibody information is needed by the Committee from previous animal studies(mice) and/or from patients who have received ZYC101a.

The PI needs to indicate to the Committee how long term follow up of the gene transfer patients will be accomplished. The followup must be done according to the FDA Guidelines which states that in addition to monitoring for clinical signs and symptoms of autoimmune disease, blood samples should be obtained before and after, and possibly during treatment as indicted, to test for the appropriate hematologic markers for determination of autoimmune disease onset.

The Committee also reviewed the Consent Form in the context of the NIH guidelines for Research Involving Recombinant DNA Molecules. Although the protocol states neither the sponsor nor the PI will be requesting autopsies on patients who die during the course of the study, Appendix MIII-B-2-c of the NIH Guidelines states, "To

obtain vital information about the safety and efficacy of gene transfer, subjects should be informed that at the time of death, no matter what the cause, permission for an autopsy will be requested of their families. Subjects should be asked to advise their families of the request and of its scientific and medical importance." NIH has samples of the actual wording for this portion of the Consent Form. Dr. Marcham will offer to assist the PI with the addition of this wording to the consent form.

In addition, lines 342 and 343 of the Consent Form should be modified to reflect that the participants will really be involved in the study of 54 weeks plus a 15 year follow up period. Recommended wording is, "You will be in the study for approximately 54 weeks. This includes a Pre-Treatment Period, a Treatment Period, and an Observation Period. In addition, you will participate in a 15-year Follow-up Period. "

On page two of the Consent Form, the approximate number of people that have used ZYZ101a should be changed from 179 to 129.

The Committee concluded that the Consent Form needed to be significantly simplified so that could be understood at an eighth grade reading level.

Decision:

Debra Chionopoulos and Dr. Marcham will work together to assist the PI with the wording on the consent form. Once the requested changes have been made and the additional information received the Committee will make a final decision regarding the approval of the protocol.

ADJOURNMENT: There being no further business, the meeting was adjourned at 11:55 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES
(Revised)

DATE: September 27, 2005

TIME: 2:00

LOCATION: BMSB 932

MEMBERS PRESENT: Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Cheri Marcham
Debra Chionopoulos
Dr. Gillian Air
Dr. Tom Kupiec

MEMBERS ABSENT: Dr. Chris Li

CALL TO ORDER: Dr. Unger called the meeting to order at 2:07 p.m.

APPROVAL OF MINUTES: The Committee reviewed the July 26, 2005 minutes. Dr. Benbrook moved to approve the minutes and Dr. Air seconded. The minutes were approved by the Committee.

The Committee reviewed the August 24, 2005 minutes. Dr. Li is to be removed from the absent list on the minutes as he was in attendance. Also, on protocols 1660 and 1661 the third sentence should read, "Then the genes of interest will be inserted back into the *P. aeruginosa* and their respective functions will be studied." Contingent on these changes, Dr. Kupiec moved to approve the minutes and Dr. Air seconded. The minutes were approved by the Committee.

TABLED PROTOCOLS:

1660 Since acceptable response received, protocol met approval requirements. Dr. Air moved to approve the protocol. Dr. Benbrook seconded.

1661 Since acceptable response received, protocol met approval requirements. Dr. Air moved to approve the protocol. Dr. Benbrook seconded.

NEW PROTOCOL APPROVAL:

1667 The date of the proposed project initiation in #7 of the protocol is 1/1/05. The Committee believes this is a typographical error that should read 10/1/05. This must be clarified and corrected by the PI. A copy of the PI's biosketch and signed SOPs are to be attached. Contingent on these changes and additions, Dr. Kupiec moved to approve the protocol. Dr. Benbrook seconded.

1671 A copy of the PI's biosketch is to be attached. Contingent on this addition, Dr. Benbrook moved to approve the protocol. Dr. Kupiec seconded.

1675 The PI submitted three protocols to the committee simultaneously. This protocol's description is identical to protocol #1671 and does not reflect TNFalpha in the description. Until the correct information regarding the protocol can be reviewed by the committee, the protocol will be tabled. The correct information from the PI can be submitted to all committee members via email for review and approval if acceptable. Dr. Kupiec moved to table the protocol. Dr. Benbrook seconded.

1668 A co-investigator is reflected on the protocol, but is not listed with any project responsibilities. Also, he did not sign the protocol. The PI will need to identify his

project responsibilities and if he is to be a co-investigator he will need to sign the protocol form. The PI and co-investigator's signatures are also needed on the SOPs.

The funding agency is listed as "Department of Funding." The Committee believes this is a typographical error. The PI will need to clarify and correct the funding agency.

The grant start date is identified as 10/1/05 and the proposed project initiation date is 9/1/05, however the project may not proceed until IBC approval is given. The PI must identify another proposed project initiation date, or indicate that the project will start upon IBC approval.

Training documentation on the hazards of both biological toxins is needed for all personnel listed on the protocol.

Contingent on these changes and additions, Dr. Marcham moved to approve the protocol. Dr. Air seconded.

1669

A co-investigator is reflected on the protocol, but is not listed with any project responsibilities. Also, he did not sign the protocol. The PI will need to identify his project responsibilities and if he is to be a co-investigator he will need to sign the protocol form. The PI and co-investigator's signatures are also needed on the SOPs.

The funding agency is listed as "Department of Funding." The Committee believes this is a typographical error. The PI will need to clarify and correct the funding agency.

The grant start date is identified as 10/1/05 and the proposed project initiation date is 9/1/05, however the project may not proceed until IBC approval is given. The PI must identify another proposed project initiation date, or indicate that the project will start upon IBC approval.

Training documentation on the hazards of both biological toxins is needed for all personnel listed on the protocol.

Contingent on these changes and additions, Dr. Air moved to approve the protocol. Dr. Kupiec seconded.

1677

The Committee has questions regarding where the mice will be infected and how the infected mice will be transported. The PI needs to clarify these issues in order for the Committee to complete the review of the protocol.

The Committee members agree the information from the PI clearing these matters should be emailed to them for review and approval, if applicable. Dr. Kupiec moved to defer approval of the protocol until such time review and approval of the additional information from the PI can be received via email. Dr. Air seconded.

HUMAN PROTOCOLS:

1573

The Committee discussed having the original *Ad Hoc* members review and continue to stay informed of all adverse events. Dr. Marcham is to contact NIH to ask what role IBC takes after receiving notification that an Adverse Event has happened on another campus.

ADJOURNMENT:

There being no further business, the meeting was adjourned at 3:49 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES
(Revised)

DATE: November 29, 2005

TIME: 2:00

LOCATION: BMSB 932

MEMBERS PRESENT: Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Cheri Marcham
Debra Chionopoulos
Dr. Gillian Air
Dr. Tom Kupiec
Dr. Chris Li

CALL TO ORDER: Dr. Unger called the meeting to order at 2:11p.m.

APPROVAL OF MINUTES: The Committee reviewed the September 28, 2005 minutes. The word discusses found under Human Protocols is to be changed to discussed. Also, *Ad hoc* is to be changed to *Ad Hoc* in the same paragraph. Dr. Kupiec moved to approve the minutes contingent on these changes and Dr. Air seconded.

NEW PROTOCOL APPROVAL:

1670 The Microorganism/Virus Usage box should be checked on the protocol. Room should be removed from the protocol as the Pseudomonas aeruginosa is already located in . is to be added to the SOPS. A copy of the PI's and Co-Investigator's biosketch are needed to be attached to the protocol. In question 11, "PhD" is indicated under relevant training/experience. Training and experience relative to this project is needed for each person listed. Contingent on acceptable responses to these changes and additions, Dr. Benbrook moved to approve the protocol. Dr. Li seconded.

1680 The Microorganism/Virus Usage box should be checked on the protocol. #34 indicates a vaccine is available for this microorganism/virus. The Committee believes this should be treatment available not a vaccine available. The PI needs to clarify where the virus will be obtained in item #28. Clarification of what will be done with the infected baboons and whether or not they will be a risk to other baboons in the colony is needed. Dr. Kupiec moved to table the protocol. Dr. Li seconded.

1686 The grant start date is to be corrected from 6/60/02. Item #39 does not reflect the total weight of the amount of toxin on hand. An answer is needed for item #45. Training documents are needed, as items #33 and #44 reflect training has not been received by all personnel. Dr. Kupiec moved to table the protocol. Dr. Air seconded.

1685 The PI needs to clarify item #16 of the protocol, as Streptolysin O is listed

twice. Intermedilysin is listed in item #36 but is omitted from #16. Item #44 is not answered, however, the SOPS were attached. Contingent on acceptable responses to these changes and additions, Dr. Benbrook moved to approve the protocol. Dr. Li seconded.

TABLED PROTOCOLS:

1675 — Since acceptable response received and protocol met approval requirements, an email vote was obtained and the protocol was approved.

PREVIOUSLY REVIEWED PROTOCOLS:

1668 — Since acceptable response received, protocol met approval requirements.

1667 — Since acceptable response received, protocol met approval requirements.

1671 — Since acceptable response received, protocol met approval requirements.

1677 — Since acceptable response received, protocol met approval requirements.

HUMAN PROTOCOLS:

1573 (Adverse Event) — Dr. Benbrook brought up the discussion again of having the original *Ad Hoc* Committee members' review and continue to stay informed of all adverse events. Dr. Marcham contacted NIH twice to ask what role IBC takes after receiving notification that an Adverse Event has happened on another campus. She has yet to receive a response. The committee members have been made aware of and discussed the adverse events. It was agreed that the Committee will not take action at this time and continue to seek guidance from NIH. Dr. Air moved to approve this action and Dr. Kupiec seconded.

CHANGES TO SELECT AGENT LIST:

The committee approved the addition of the 1918 Pandemic Influenza Virus to the Select Agent List on the IBC protocol form.

ADVERSE BIOSAFETY EVENT REPORT FORM:

The Committee approved the modified form. Dr. Benbrook moved to approve and Dr. Air seconded.

ADJOURNMENT: There being no further business, the meeting was adjourned at 3:44 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES
(Revised)

DATE: December 16, 2005

TIME: 2:00

LOCATION: BMSB 932

MEMBERS PRESENT: Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Cheri Marcham
Dr. Gillian Air
Dr. Tom Kupiec
Dr. Chris Li

ABSENT: Debra Chionopoulos

OTHERS IN ATTENDANCE: Dr. Nicole Vu

CALL TO ORDER: Dr. Unger called the meeting to order at 2:10p.m.

Dr. Kupiec introduced Dr. Nicole Vu to the Committee. Dr. Vu will be taking Dr. Kupiec's place on the Committee for an undetermined amount of time. Dr. Kupiec met with Dr. Unger prior to the meeting and discussed Dr. Vu's qualifications. Dr. Unger interviewed Dr. Vu prior to the meeting also.

APPROVAL OF MINUTES: The Committee reviewed the November 29, 2005 minutes. Dr. Benbrook moved to approve the minutes and Dr. Air seconded. The minutes were approved.

NEW PROTOCOL APPROVAL:

1688 The Committee had several questions regarding this protocol. In question 12, the form asks for the biological source of the DNA/RNA. The PI does not indicate the species of origin of the Math-1 gene, (e.g., is it from a human, rat, chinchilla)? Also, what kind of protein is Math-1 (e.g., is it a transcription factor)? The construct also contains genes from the plasmid which is used in its construction - what sequence or elements from the plasmid are in the construct?

The Committee requests further information on the hazards associated with inadvertent exposure to personnel to nanoparticles of Fe3O4 and this construct? Can it become airborne (aerosolized) at any time in the process of this experiment? Can it be absorbed through the skin? When the suspension of conjugated MNPGPs is infused at a rate of 3 ul/minute, is there excess liquid that is not taken up? In question 18, regarding safety concerns to animal handlers, the PI responded that BSLII procedures will be followed. These may be good guidelines as a start, but the Committee would like for the PI to prepare specific procedures that will be used for specific tasks rather than just attaching the list of BSL2 guidelines. For example, on page 4 of the

attachment, where transfection of the inner ear is discussed, particular safety procedures that will be taken for this procedure are not indicated. The Committee is interested in the potential hazards to technicians associated with this process, and what safety equipment, if any, will be needed for the procedure. How is the fluid actually injected, and is there any chance of aerosolization of the material? If so, some protection needs to be provided. The animal SOP form should be completed outlining the issues that should be addressed. Training documentation for all lab personnel regarding the SOPs is to be provided to the IBC.

On page 3 of the attachment, the PI stated that "Plasmids will be amplified in E. coli in the (IBC approved) laboratories of ." As grant proposals and projects are approved by the IBC and not laboratories, this particular amplification process will need to be submitted to the IBC for approval by whichever PI will perform the project, as none is currently on file.

Dr. Benbrook moved to table the protocol. Dr. Air seconded. The protocol was tabled.

1689 Dr. Benbrook moved to approve the protocol. Dr. Li seconded. The protocol was approved.

1690 Dr. Air moved to approve the protocol. Dr. Li seconded. The protocol was approved.

TABLED PROTOCOLS:

1680 Since acceptable response received, protocol met approval requirements. Dr. Benbrook moved to approve the protocol. Dr. Air seconded.

1686 Since acceptable response received, protocol met approval requirements. Dr. Li moved to approve the protocol. Dr. Air seconded.

PREVIOUSLY REVIEWED PROTOCOLS

1670 Since acceptable response received, protocol met approval requirements.

1685 Since acceptable response received, protocol met approval requirements.

ADJOURNMENT: There being no further business, the meeting was adjourned at 3:44 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary

The University Of Oklahoma Health Sciences Center
Institutional Biosafety Committee
MINUTES

DATE: January 31, 2006

TIME: 2:00

LOCATION: BMSB 932

MEMBERS PRESENT:
Dr. Leon Unger, Chair
Dr. Doris Benbrook, Vice Chair
Dr. Cheri Marcham
Dr. Gillian Air
Dr. Nicole Vu
Dr. Chris Li
Debra Chionopoulos

CALL TO ORDER: Dr. Unger called the meeting to order at 2:17p.m.

APPROVAL OF MINUTES: The Committee reviewed the January 31, 2006 minutes. Dr. Unger requested that the minutes reflect the fact that he and Dr. Kupiec had discussed Dr. Vu's qualifications prior to the meeting. The minutes should also indicate that Dr. Unger had interviewed Dr. Vu prior to the meeting. Dr. Li moved to approve the minutes contingent on these additions and Dr. Vu seconded.

NEW PROTOCOL APPROVAL:

1692) The Committee had several questions regarding this protocol The PI should specify the plasmids to be used in question 13 is listed in the SOPs but not anywhere else in the protocol. Should it not be listed in #4, #29 and #30 also? #49 is to be answered. In addition, the PI must sign the SOPs.

The Committee requests further information on the tissue hood. Is it a laminar flow hood or a biosafety cabinet?

More specific training relevant to the project is needed for the PI and the other laboratory employees in question 11. Also, in questions 11, the lab technician's name is spelled incorrectly.

Dr. Benbrook moved to table the protocol until such time as these items are rectified. Dr. Air seconded. The protocol was tabled.

1694 Room 1032A is listed in the SOPs but not anywhere else in the protocol. #16 should be marked "yes". #12 should be marked to indicate whether human blood/tissue will be handled by laboratory personnel.

The Committee requests further information on the tissue hood. Is it a laminar flow hood or a biosafety cabinet?

More specific training relevant to the project is needed for the PI and the other laboratory employees in question 11. Also, in questions 11, the lab

technician's name is spelled incorrectly. In addition, the PI must sign the protocol and the SOPs. Dr. Benbrook moved to table the protocol until such time as these items are rectified. Dr. Air seconded. The protocol was tabled.

1700 — Dr. Li moved to approve the protocol. Dr. Benbrook seconded. The protocol was approved.

TABLED PROTOCOLS:

1688 — Since acceptable responses received, protocol met approval requirements. Dr. Benbrook moved to approve the protocol. Dr. Li seconded.

HUMAN PROTOCOLS

1701 — Dr. Air commented that the information provided was very complete and comprehensive. The Committee had a few conditions that they wanted the PI to be aware of. Safe Needle devices should be used whenever possible for the administration of the drug. Any changes to the protocol are to be reviewed and approved by the IBC. Any employee added to the protocol should be trained on the SOPs before performing any work associated with the protocol. Any adverse events occurring at the clinical trial site are to be reported to the IBC using the appropriate form found on the IBC web site. Copies of reports of adverse events at other clinical trial sites should be forwarded to the IBC as well as the IRB. Dr. Air moved to approve the protocol contingent of the PI being notified of these conditions. Dr. Benbrook. seconded. The protocol was approved.

IND SAFETY REPORTS

1573 — The Committee agreed that the *Ad Hoc* Committee members for this protocol will be sent the safety reports for their review and comments.

1607 — The Committee agreed that the *Ad Hoc* Committee members for this protocol will be sent the safety reports for their review and comments.

Response from NIH — The Committee reviewed the response from NIH regarding the IBC's role in serious adverse events. As discussed by the Committee, *Ad Hoc* Committee members will start receiving all serious adverse event information relevant to the protocol they were involved in.

ADJOURNMENT: — There being no further business, the meeting was adjourned at 3:42 p.m.

Respectfully submitted,

Andrea Kyker
Recording Secretary