



THE UNIVERSITY OF TEXAS SYSTEM

Office of General Counsel

201 WEST SEVENTH STREET AUSTIN, TEXAS 78701-2902

TELEPHONE (512) 499-4462

FAX (512) 499-4523

Carol Longoria
Public Information Coordinator

April 4, 2006

Honorable Greg Abbott
Attorney General of Texas
Open Records Division
Price Daniel Building
209 W. 14th Street, 6th Floor
Austin, Texas 78701

**Re: Public Information Request #14 from Edward Hammond to the University of Texas
Medical Branch at Galveston**

Dear General Abbott:

On March 21, 2006, the University of Texas Medical Branch at Galveston (UTMB or "University") received a request for information from Edward Hammond (**TAB 2**). Originally, Mr. Hammond submitted a request via fax to Dr. Miles Cloyd, Chairman of the UTMB Institutional Biosafety Committee. This fax was received by Dr. Cloyd on March 15, 2006. Chris Johnsen, an attorney in the UTMB Office of Legal Affairs, replied to Mr. Hammond and asked that he submit his inquiry to the University's Public Information Officer.

In OR2006-01461 your office ruled on the process by which email and faxed communications trigger the requirements imposed by the Texas Public Information Act ("Act"). That ruling states:

The Act's disclosure requirements are generally triggered by a governmental body's receipt of a written request for information. See Gov't Code § 552.301(a). However, in instances where a written request is submitted to a governmental body by facsimile transmission or through e-mail, the Act, as you note, specifically provides that the request be "sent to the officer for public information, or the person designated by that officer[.]" Id. § 552.301(c). Thus, for written requests that are submitted to a governmental body via facsimile or e-mail, the Act's disclosure requirements are triggered only if the request is sent to the governmental body's "officer for public information," or by a person designated by that officer to receive such requests.

April 4, 2006

Page 2 of 5

In this case, you state that the first request was addressed and emailed to the Dean of the university's law school. You further state that the Dean is neither the university's "officer for public information," nor the "person designated by that officer." See Gov't Code § 552.201 (officer for public information is defined as chief administrative officer of governmental body). We thus conclude that the first e-mailed request at issue here was not a proper request under the Act, and the university need not respond to this request as it failed to comply with the Act.

Because the first request was sent via fax to Dr. Cloyd who is neither the University's Public Information Officer nor his designee, it did not trigger the Act. Only when Mr. Hammond finally submitted his request to UTMB's Public Information Officer, Mr. Richard Moore, did the University have any obligation to respond in accordance with the deadlines imposed by the Act.

Although the requestor argues that his request is submitted pursuant to the guidelines imposed by the National Institutes of Health ("NIH"), these guidelines do not have the force of law, nor do they provide a specific framework to which agencies can adhere in responding to requests for information. Moreover, under Texas law, the Act is the mechanism by which the public has access government documents. There is no separate process utilized for NIH documents.

In addition, if a requestor seeks documents that we consider confidential, it must be handled pursuant to the Act so that the Office of the Attorney General ("OAG") has jurisdiction to rule on the public or non-public nature of the information. Because UTMB utilizes the framework outlined by statute in response to requests for public information, the University's request that Mr. Hammond submit his inquiry so as to trigger the Act is appropriate and lawful. As this requestor has submitted at least thirteen (13) previous requests to the University and other System campuses, generally seeking the same type of information each time, these requirements of law are not unfamiliar to Mr. Hammond.

UTMB subsequently forwarded this request to the University of Texas System (U. T. System or "System") for handling with your office. In compliance with Section 552.301, *Texas Government Code*, we now send this request for decision within ten business days from the request receipt date. Additionally, we have also sent notice of our request (TAB 3) and a copy of this letter to the requestor in accordance with Section 552.301(d), *Texas Government Code*.

The request asks the University to produce the following documents:

"...the Minutes of all meetings of the University of Texas Medical Branch Institutional Biosafety Committee (IBC) since 1 May 2003."

On May 15, 2003, the OAG issued OR2003-3283 in response to one of many public information requests submitted to UTMB over time by Mr. Hammond's Sunshine Project. Numerous times

April 4, 2006

Page 3 of 5

Mr. Hammond has requested minutes of UTMB's Biological Safety Committee ("BSC")¹. In the noted ruling your office determined that the committee's minutes were confidential by law and could not be released. Since that time, UTMB has worked with the NIH to determine how UTMB could produce minutes from its BSC and not violate Texas law.

To facilitate a solution, U. T. System Administration created a BSC originating in the System office. The first meeting of the System BSC was in December 2004. For several months, UTMB utilized both the U. T. System BSC for research that the NIH mandated having minutes available to the public, and the original UTMB BSC for all other research not regulated by the NIH Guidelines. In January 2005 UTMB dissolved its UTMB BSC and now utilizes the System BSC for all research requiring BSC review and approval.

There are, consequently, three separate time periods relevant to this request:

- From May 2003 through November 2003 the same BSC structure existed at UTMB as existed when OR2003-3283 was issued. Because the UTMB BSC was a medical committee, we believe that all minutes from this period are confidential by law and cannot be released. A representative sample is enclosed in **TAB 4**.
- From December 2003 through December, 2005 dual BSCs existed during this period. All minutes by the UT System BSC are public and have been produced to the requester. UTMB believes that all responsive minutes from the UTMB BSC are analogous to those covered by OR2003-3283, and thus confidential by law. A representative sample is enclosed in **TAB 5**.
- From January 2005 through the present only the UT System BSC existed; thus all responsive minutes are public and have been produced.

Accordingly, the University asserts that Section 552.101, *Texas Government Code* excepts from disclosure all the requested meeting minutes from May 2003 through November 2003, and similarly protects the UTMB BSC minutes dated December 2003-December 2005. From December 2003 forward, all the System BSC minutes are not at issue.

Under Section 552.101 of the Act, information is excepted from disclosure if it is "information considered to be confidential by law, either constitutionally, statutorily or by judicial decision." UTMB asserts that under Section 51.914(1), *Texas Education Code*, and Section 161.032, *Texas Health and Safety Code*, the information responsive to this request is confidential by law and, therefore, excepted from disclosure in accordance with Section 552.101 of the Act.

The subject meeting minutes comprises records and proceedings of UTMB's BSC. It is the position of UTMB that **all records generated by the BSC** are confidential by statute. The BSC is

¹ UTMB refers to its Institutional Biosafety Committee as the "Biological Safety Committee" or "BSC," not as "IBC."

April 4, 2006

Page 4 of 5

a university medical center or health science center committee established to oversee biological research activities pursuant to 45 C.F.R. Section 46.103; therefore documents generated in conjunction with this committee **are protected from disclosure** under Section 161.032, *Health and Safety Code*, and Section 552.101, *Texas Government Code*.

Under the provisions of Section 161.032(a), *Health and Safety Code*, a “medical committee” includes any committee or joint committee of a hospital, medical organization, university medical center or health science center. Section 161.032(a) specifically makes the records and proceedings of a medical committee, including meeting minutes, not subject to court subpoena and protected from disclosure under the Act. See OR2001-0912 and OR2002-6791.

Alternatively and to the extent that details contained in the minutes reveal the substance of UTMB research, Section 51.914(1) of the *Texas Education Code* makes confidential by law certain information falling within *either* of the following two groups: (i) technological and scientific information; *or* (ii) information that relates to a product, device, or process (or the application or use of such a product, device, or process). To be afforded protection under this provision, the information at issue must have been developed by an institution of higher education and have a potential for being sold, traded, or licensed for a fee (*regardless* of whether it is patentable or capable of being registered under copyright or trademark laws).

UTMB is an institution of higher education (as defined in *Texas Education Code* Section 61.003(8)). It is a multi-faceted medical institution incorporating outstanding integrated programs in patient care, research, education, and prevention. The goal of Section 51.914(1) is to protect the actual or potential value of proprietary information of institutions of higher education, such as UTMB. Tex. Educ. Code Ann. § 51.914.

The requested meeting minutes contain details of procedures, data, and other information that relate to a product, device, or process (or the application of such) developed by UTMB and/or in collaboration with several other researchers and institutions. This information falls within both groups of information protected under Section 51.914(1) of the *Texas Education Code*. Please note that portions of this information are also protected under Section 51.914(2) of the *Texas Education Code*, particularly any details that directly reveal the substance of the research and permit third parties to appropriate such research. See, Tex. Att’y Gen. ORD- 497; Tex. Att’y Gen. ORD- 557.

The type of information reflected in the responsive material does have the potential for being sold, traded, or licensed for a fee. Research discoveries and inventions are a product of the data collected and developed by the researchers. In addition to conducting its own research using the subject information, UTMB can potentially sell or license this information for a fee to other researchers, or third parties interested in similar studies. See, Tex. Att’y Gen. ORD-651

The data included as part of these types of meeting minutes is precisely the information from which research discoveries are made in conjunction with the scientific information, products,

April 4, 2006

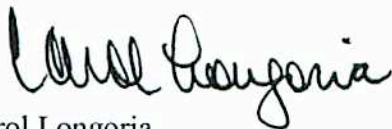
Page 5 of 5

devices, and processes developed by UTMB's sponsored and cooperative research activities. For these reasons, the University asserts that all such information is also confidential by statute under Section 51.914(1), *Texas Education Code* and, therefore, excepted from disclosure in accordance with Section 552.101 of the Act.

In conclusion, the University of Texas Medical Branch at Galveston seeks an *opinion from your office* on the applicability of Sections 552.101, *Texas Government Code*. With this request for decision, we are notifying the OAG that we will withhold some responsive documents pending review by your office. All interested parties are listed below.

If you need additional information, please do not hesitate to contact me at (512) 499-4521.

Sincerely,



Carol Longoria

Enclosures


INTERESTED PARTIES:

Component:

Mr. Chris Johnsen
UTMB at Galveston
Legal Affairs
301 University Blvd.
Room 4.254 Rebecca Sealy Hospital
Galveston, Texas 77555-0171

cc:

Requestor:



Mr. Edward Hammond
The Sunshine Project
P.O. Box 41987
Austin, TX 78701
(w/o enclosures)



OFFICE OF THE VICE PRESIDENT
FOR BUSINESS AND ADMINISTRATION

March 29, 2006



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

Re: Response to Public Information Act Request #18 dated March 21, 2006

Dear Mr. Hammond:

This will serve as The University of Texas Medical Branch at Galveston's response to your Public Information Act Request dated March 21, 2006 for "the Minutes of all meetings of the University of Texas Medical Branch Institutional Biosafety Committee (IBC) since 1 May 2003."

Enclosed are copies of the minutes from the University of Texas System Institutional BioSafety Committee at Galveston for December 16, 2003 through February 3, 2006.

70 copies at \$0.10/copy	\$ 7.00
1 hours labor at \$15.00/hour	\$15.00
Overhead on labor charge (20%)	<u>\$ 3.00</u>
Total costs	\$25.00

Please make any check payable to the "University of Texas Medical Branch" and in the memo portion, please note "Hammond #18 PIA" and mail to Mr. Chris Johnsen at The University of Texas Medical Branch at Galveston, Legal Affairs, 301 University Blvd., Galveston, Texas 77555-0171.


Mr. Edward Hammond

March 29, 2006

Page 2

This letter also serves as notice that we are requesting an opinion from the Office of the Attorney General of Texas on whether the minutes from the UTMB Biological Safety Committee (as opposed to the University of Texas System IBC) from May 15, 2003 through December 2005 must be withheld pursuant to Section 552.101 of the Government Code. See Attorney General Opinion OR2003-3283.

Sincerely,



Richard S. Moore
Vice President for Business and Administration

Content reviewed


RSM:bmw

Xc: Chris Johnsen
Legal Affairs



The University of Texas System
Nine Universities. Six Health Institutions. Unlimited Possibilities.

Institutional BioSafety Committee at Galveston

MINUTES
February 3, 2006

The Institutional BioSafety Committee met on Friday, February 3, 2006, and called to order at 2:05PM in Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nelson Avery, M.D.
Alan Barrett, Ph.D.
Robin Brinkmeyer, Ph.D.
Miles Cloyd, Ph.D.
Jim Ditty, Ph.D.
Amy Goebel, CIH
Miguel Grimaldo
Peggy Mann, M.S., M.T.
Wayne Patterson, Ph.D.

Johnny Peterson, Ph.D.
Norbert J. Roberts, M.D.
Karen Vargas, DVM
Scott Weaver, Ph.D.
Thomas Wood, Ph.D.

MEMBERS ABSENT

Dana Wiltz-Beckham, DVM
Nigel Bourne, Ph.D.
Juan P. Olano, M.D.
Tonia Eaves-Pyles, Ph.D.
Jeffrey Rabek, Ph.D.
Kenneth I. Shine, M.D.
Claudio Soto, Ph.D.
Douglas Watts, Ph.D.

GUEST

Anne-Sophie Brocard, Ph.D.

Present Ex-Officio-Non-Voting

Dee Zimmerman
Chris Johnsen

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I.

APPROVAL OF MINUTES

The minutes of the January 6, 2006 meeting were approved with no changes.

II. NEW BUSINESS

Norbert Herzog, Ph.D.

Dr. Herzog is submitting an NOU to work with Lassa Nucleocapsid Protein Expression Plasmids. Since Lassa is listed as a select agent, the Committee discussed the need to have information on the source of the plasmids included with the NOU.

The Committee approved the NOU with the following requested condition:

- Provide information on the source of the plasmids

There was one abstention.

Norbert Herzog, Ph.D.

Dr. Herzog is submitting a new NOU to work with Vaccinia Virus expressing the Lassa Fever Virus Glycoprotein.

The Committee discussed the safety issues regarding the use of a phenolic germicidal vs. the potential health affect to laboratory staff. The Committee did not feel that the use of a phenolic was warranted. Both Cavicide (quaternary ammonia with isopropyl alcohol) and bleach solutions are appropriate disinfectants for the material in use and do not present the safety risks associated with phenolics. Use of a phenolic germicidal was not approved. It was also noted that the personnel protective equipment (PPE) check off did not include use of a lab coat. The Committee felt that this was simply a clerical mistake but noted the correction to the PPE.

The Committee approved the NOU with the following conditions:

- Cavicide and 10% bleach are to be used for decontamination
- Use of lab coat noted in the PPE check off
- Contact Employee Health Clinic, Dr. Nelson Avery regarding small pox vaccine

There was one abstention.

Norbert Herzog, Ph.D.

Dr. Herzog is submitting an NOU to work with Pichinde Virus.

After review of the NOU, the Committee approved the NOU with no conditions.

There was one abstention.

The General Safety Compliance Analysis of Laboratory Audits for the reporting period of 2005 was distributed to the Committee. The Committee reviewed the data for laboratory audits performed by Environmental Health and Safety/Biological and Chemical Safety Program.

Clarifications received from CDC Ft. Collins, Colorado and the CDC Select Agent Program on the status of select agent viral lysates and cDNA clones was received. 42 CFR Part 73.4 (f) (2) states that non-viable select agent organisms are excluded from the regulations. Lysates are exempt from the select agent regulations if they are non-viable. The nucleic material would have to be a form that is infectious before it is regulated. Since additional laboratory manipulation is required for cDNA to become infectious, it is not subject to 42 CFR 73.3. (c) and 73.4(c). The BSL2 laboratories that meet these criteria would not have to be registered as select agent users. This would allow for these labs to be "de-registered" with the CDC alleviating the cost of additional security and accessibility of the lab. The Committee agreed that there was no risk of infection from cDNA material, however the Committee also indicated that storage of purified RNA would be handled as a select agent. If the lab were de-registered then storage of purified RNA material from select agent organism would not be permitted in the BSL2 labs.

A motion was made that the Committee approve the CDC clarifications presented regarding genomic materials and lysates. Select agent laboratories at UTMB could request de-registered from security requirements if the research meets the clarifications. All Committee members were in favor.

NIH Office of Biotechnology Activities Continuing Education

OBA News from the NIH Office of Biotechnology Activities, January 18, 2006 regarding Reporting Recombinant DNA Research-Related Accidents or Violations of NIH Guidelines were shared with Committee. The purpose of the OBA News item is to remind IBCs about the requirement and to clarify proper implementation.

Outlined in the NIH guidelines for Recombinant DNA are reporting requirements to the NIH of research related accidents and illnesses as well as adverse effects of human gene therapy. Under the NIH guidelines any adverse effect from the clinical trial involving a human gene transfer is required to return to the IBC for review. Following normal UTMB procedure, any adverse effect during gene therapy clinical trial would be reported to the IRB, which in turn will report it to the IBC. The report will be reviewed jointly. The Committee expressed concern regarding patient confidentiality issues, since the Institutional BioSafety Committee (IBC) is no longer a medical committee. The IRB liaison for the IBC indicated that this should not be an issue, as confidential patient information can be blacked out from the report. The IBC has reviewed and approved human gene therapy protocols previously; however, there are no active protocols at this time.

The IBC policy will be amended accordingly to reflect joint review by both the IBC and IRB. The revised policy will be presented to the IBC members for review.

An incident that occurred last month in the BSL4 that resulted from an individuals suit malfunctioning was reported. The connection from the air line into the positive pressure suit had become disassembled. The individual wearing the suit immediately covered it with his hand, followed by duct tape and then exited from the laboratory using normal exit procedures. The suit remained positive and there were no pathogens being used at the time of the incident.

The BSL4 sub-committee for potential exposure was convened to review the incident. This incident was deemed a level II low risk since it was more than just a minor breach of the suit. The subcommittee recommended that the individual report to Employee Health Clinic instituting Level II follow-up procedures (including fever monitoring) even though the risk of exposure was minimal. This incident will be used as the required select agent emergency response accident training.

A brief description of the UTMB procedures for the weather shutdown that occurred for hurricane Rita was given. The post-storm follow-up from Dr. Stobo will be provided to the Committee. A short outline of the hurricane shutdown procedures for containment laboratories was provided to the Committee. A community representative on the IBC did share with the Committee that there have been questions by community members as well as students regarding the BSL4 and the GNL. There is still a misconception about the choice of Galveston for both BSL4 and the GNL construction. It was suggested that additional public meetings and community discussions on this subject would continue to support good public relations. The IBC indicated that speakers are available to talk to both community members and students to answer any questions that they might have.

The following NOU for Human Products were approved:

- William Au, Ph.D. was approved for cell cultures with the condition that 10% bleach be used for decontamination and spill clean up.
- Manubai Nagamani, M.D. was approved for tissue/bone, blood, serum, body fluids and cell cultures.
- Norbert Herzog, Ph.D. was approved for cell cultures.

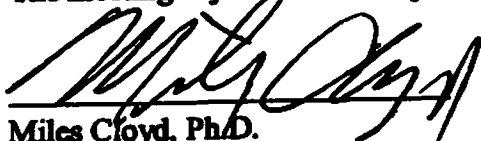
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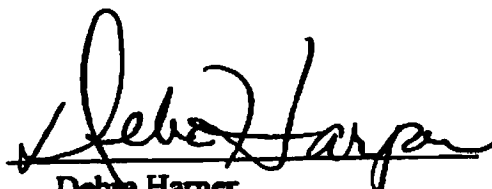
OLD BUSINESS

None

IV. Other Business

The meeting adjourned at 3:40pm.


Miles Cloyd, Ph.D.
Chairman


Debra Harper
Recording Secretary



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Institutional BioSafety Committee at Galveston

MINUTES
January 6, 2006

The Institutional BioSafety Committee met on Friday, January 6, 2006, call to order at 2:05PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nelson Avery, M.D.
Nigel Borne, Ph.D.
Miles Cloyd, Ph.D.
Jim Ditty, Ph.D.
Amy Goebel
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Johnny W. Peterson, Ph.D.
Norbert Roberts, M.D.
Wayne Patterson, Ph.D.

Bruce Schoenbucher, ISO
Karen Vargas, DVM
Douglas Watts, Ph.D.
Alan Barrett, Ph.D.
Thomas Wood, Ph.D.
Claudio Soto, Ph.D.
Robin Brinkmeyer, Ph.D.
Dana Wiltz-Beckham, DVM
Miguel Grimaldo
Anne-Sophie Brocard, Ph.D.

MEMBERS ABSENT

Scott Weaver, Ph.D.
Jeffrey Rabek, Ph.D.
Tonia Eaves-Pyles, Ph.D.
Kenneth I. Shine, M.D.

GUEST

Jim Stone
Jet Newton

Present Ex-Officio-Non-Voting

Dee Zimmerman
Chris Johnsen

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I.

APPROVAL OF MINUTES

The minutes of the December 2, 2005 meeting were approved, with changes.

II.

NEW BUSINESS

Zhihua Zou, Ph.D.

Dr. Zou is submitting a new NOU to work with recombinant adeno-associated virus, all viral genes deleted and encoding a plant protein Barley Lectin. The Committee discussed Dr. Zhou's reason for stating that animals are to be housed in ABSL1 with administration of agent at ABSL2 using a biosafety cabinet. The

1

Committee discussed that after dosing, the animal will not excrete any infectious genes. There is no danger of transmission between animal and lab technicians after animal has been dosed. The MSDS that was submitted with the NOU is not appropriate to the agent being used.

The Committee approved the NOU with the following requested condition:

- NOU submitted for replication incompetent AAV. MSDS submitted is for the wild type AAV. If appropriate Biological MSDS is not available please state "not available".

Thomas Albrecht, Ph.D.

Dr. Albrecht is submitting a renewal of his NOU to work with Human Immunodeficiency virus (HIV) and Hepatitis C virus (HCV). Committee asked where liver tissue from infected animals will come from. The committee tabled the NOU. The Committee requested the following information:

- Add Herpes Virus to list of agents or remove from description.
- Provide a more detailed description of use.
- Please clarify in what form liver tissues are received (fixed tissue, homogenized tissue, solid tissue blocks)
- Clarify that needle sticks, splash and aerosol are the mode of transmission for all agents listed.
- Clarification requested regarding the ability to maintain the HIV without continuing propagation of the cultures.
- Move transportation of agent to the Description of Use.
- Proper PPE should include lab coats, please change accordingly.
- In Section II rDNA, separate source of rDNA.
- In Section II rDNA -f, etc. denotes additional information, please provide that information. Please note that the question asks if the gene alters the cycle, if yes specify how this occurs.

Thomas Albrecht, Ph.D.

Dr. Albrecht is submitting a renewal of his NOU to work with Human cytomegalovirus (HCMV), herpes simplex virus 1 and 2, varicella-zoster virus, Epstein-Barr virus, (SV40, adenovirus and para-adenovirus hybrids are used as controls). Committee discussed whether there is need for the Hepatitis B vaccine in this NOU. Committee questioned how agent will be transported. The Committee tabled the NOU. The Committee requested the following information:

- Description must include all agents listed.
- Clarify how listed controls are procured and cultured – if cultured or manipulated an NOU submission will be required.
- Laboratory transmission must be provided for all agents.
- Section I Question 10 – remove check for "other" and place information in Section I Question 3.
- Agent transport should be moved from to Description of Use, and source of agents needs to be verified.
- Section II rDNA - complete responses to h and k.



- Agent transport should be moved from to Description of Use, and source of agents needs to be verified.
- Section II rDNA - complete responses to h and k.

Michael Holbrook, Ph.D.

Dr. Holbrook is submitting a NOU to work with Influenza virus, strain H5N1. The Committee discussed proper procedures for nebulizer treatment. Also the Committee discussed whether the agent is being administered intranasally. The Committee approved the NOU with the following condition:

- Please provide number of years that personnel have working with animals.

Michael Holbrook, Ph.D.

Dr. Holbrook is submitting an NOU for BSL4 training. The NOU will be used as a base for training in the Robert E. Shope Laboratory. The training is provided in three phases: Phase 1 includes an evaluation of the trainees past experience in handling pathogens at BSL3 and animals at ABSL3 and an assessment of his/her knowledge in the BSL4 and SOP manual as well as a review of safety procedures by EHS. Phase 2 includes but is not limited to facility training; daily check list, as well as the proper use of the BSL4 suits, decontamination methods, entering and exiting procedures and record keeping. Phase 3 involves laboratory training under the supervision of an approved mentor. In order to complete the training a new user needs a minimal of 40 entries and 100hrs in-lab suit time. An experience user needs a letter of recommendation from his/her previous BSL4 facility as well as a minimal of 10 entries and 25hrs in-lab suit time, BSL4 facility (non-research) are required to have a minimum of 20 entries and 50hrs in-lab suit time. The Committee approved the NOU with no conditions.

The following NOU for Human Products were approved administratively:

- Xiadong Cheng, Ph.D. was approved for blood, serum. Body fluids, and cell cultures.
- Yuan-Lin Dong, M.D., Ph.D. was approved for tissue/bone, blood, serum. Body fluids and cell cultures.
- Lisa Gould, M.D., Ph.D. was approved for tissue/bone and cell cultures.
- Randall Goldblum, M.D. was approved for blood, serum, body fluids and cell cultures.
- Luis Martinez, Ph.D. was approved for cell cultures with the condition that Hepatitis B vaccine is recommended.
- Rinat Esenaliev, Ph.D. was approved for cell cultures.
- William Au, Ph.D. was approved for cell cultures.

The request for immunizations was approved.

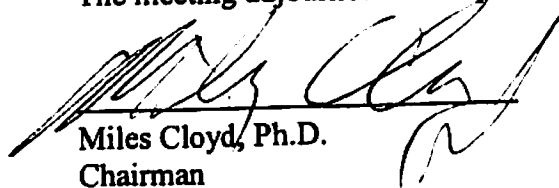
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OLD BUSINESS

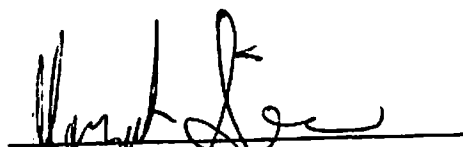
Dr. Motin responded to the conditions set forth by the Committee.

IV. Other Business

The meeting adjourned at 3:50pm.

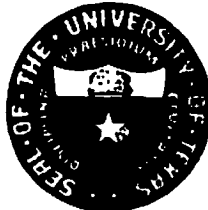


Miles Cloyd, Ph.D.
Chairman



Margaret Gibbons
Recording Secretary

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THE UNIVERSITY OF TEXAS SYSTEM

Office of the Chancellor

601 COLORADO STREET AUSTIN, TEXAS 78701-2982

University of Texas System

Office of Health Affairs

601 Colorado Street

Austin, Texas 78701

Telephone (512) 499-4224 Fax (512) 499-4313

MINUTES

December 2, 2005

The Institutional BioSafety Committee met on Friday, December 2, 2005 call to order at 2:05PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nelson Avery, M.D.

Nigel Borne, Ph.D.

Miles Cloyd, Ph.D.

Jim Ditty, Ph.D.

Amy Goebel

Peggy Mann, M.S., M.T.

Juan P. Olano, M.D.

Johnny W. Peterson, Ph.D.

Norbert Roberts, M.D.

Bruce Schoenbucher, ISO

Karen Vargas, DVM

Douglas Watts, Ph.D.

Scott Weaver, Ph.D.

Thomas Wood, Ph.D.

MEMBERS ABSENT

Alan Barrett, Ph.D.

Robin Brinkmeyer, Ph.D.

Tonia Eaves-Pyles, Ph.D.

Miguel Grimaldo

Dana Wiltz-Beckham, DVM

Wayne Patterson, Ph.D.

Jeffrey Rabek, Ph.D.

Kenneth I. Shine, M.D.

Claudio Soto, Ph.D.

GUEST

Jim Stone

Jet Newton

Donald H. Bouyer, Ph.D.

Vladimir Motin, Ph.D.

Jennilee Robinson

Present Ex-Officio-Non-voting

Dee Zimmerman

Chris Johnsen

I. APPROVAL OF MINUTES

The minutes of the November 4, 2005 meeting were approved.

II. NEW BUSINESS

Vladimir Motin, Ph.D. submitted a new NOU for *Exempt strains of Yersinia pestis, control laboratory strains of E. coli and enteropathogenic Yersinia Y. pseudonuberculois and the rat flea, Xenopysylla cheopis.*

Dr. Motin, Jennilee Robinson and Donald H. Bouyer, Ph.D. were present at the meeting. Jennilee Robinson presented guidelines for working in the flea insectary and the SOP's for the committee members.

The Committee approved the NOU with the following requested conditions:

- Follow Employee Exposure procedures for reporting insect bites
- Include approved head cover in PPE to be used at all times
- Provide appropriate SOP to respond to the accidental escape of fleas

Reuben Matalon, M.D., Ph.D., submitted a renewal NOU for *rAAV/ASP-Adeno o adeno associated viruses carrying c-DNA to correct canavan deficiency/aspartoacylase*.

The Committee approved the NOU with the following requested condition:

- Provide a list of vectors

Peter Mason, Ph.D. submitted a new NOU for *Yellow fever virus*.

The Committee approved the NOU with the following conditions:

- Provide location of biosafety cabinet room
- IACUC approval is needed for animal work

C. J. Peters, M.D. submitted a new NOU for *Nipha virus DNA/RNA*. The Committee approved the request with no conditions.

C. J. Peters, M.D. submitted a new NOU for *Junin virus vaccine strain Candid #1*. The Committee approved the request with no conditions.

E. Brad Thompson, M.D. submitted a NOU renewal for *Adeno, Lenti, and Sindbis virus*.

The Committee approved the NOU with the following condition:

- IACUC approval is needed for animal work

Thomas Wood, Ph.D. submitted a NOU renewal for *Brain: HCNIA, HCN2A, CCF-STTG1, Colan: Ls180, HC116, CaCo2, CC018Co, HT29, Colo320, Leukemia: Jurkat, HL-60, IG-1, RAJ, H9, Muscle: HEMS (Primary) Misc: HS27, HOS, WIL2NS, HUV-EC-C, Katolll, Hu293 tet-on, RPE, HEK TsA-201*
Murine: NIH3T3, FG-10, 4903T, H2, CRL1658, NIH3T3 tet-off, NIH3T3, MRXRSB, Rat and Chinese Hamsters: CHOK1, CHOS, CHHO-AA8 TET-OFF, PC 12, Mink: MV1Lu TK', Simian: COS-1 COS-7, Vero, Feline: G355-5 G355 (CRL2033), PG4, FEF, CRFK, Retroviral Vector/Packaging: PE501, PA317, PG13, PA17, MSXRBS, PE501 MSXRBS, G355-5 MSXRBS, INSECT: Sf9, Chicken: UMNSAH, DF-1

The Committee approved the request with no conditions.

The following NOU for Human Products were approved administratively:

Satish K. Srivastava, Ph.D. was approved for cell cultures.

E. Brad Thompson, M.D., was approved for tissue/bone, blood, serum, body fluids and cell cultures.

Roberto Garofalo, M.D., was approved for blood, serum, body fluids and cell cultures.

Dai H. Chung, M.D. was approved for cell cultures.

Kelly Dineley, Ph.D., was approved for blood, serum, body fluids and cell cultures.

Amin A. Mohammad, Ph.D. was approved for blood, serum, body fluids.

Douglas Paddon-Jones, Ph.D. was approved for tissue/bone, blood, serum, body fluids.

Binhua (Peter) Zhou, Ph.D. was approved for cell cultures.

Luis Martine, Ph.D. was approved for cell cultures.

William J. Calhoun, Ph.D. was approved for tissue/bone, blood, serum, body fluids and cell cultures.

Thomas Albrecht, Ph.D. was approved for tissue/bone and cell cultures.

Michael Smith, Ph.D. was approved for tissue/bone blood, serum, and body fluids.

Dr. Ashok Chopra requested to add additional new staff members.

Dr. Tonyia Eaves-Pyles requested to add additional new staff members

The requests for immunizations were all approved.

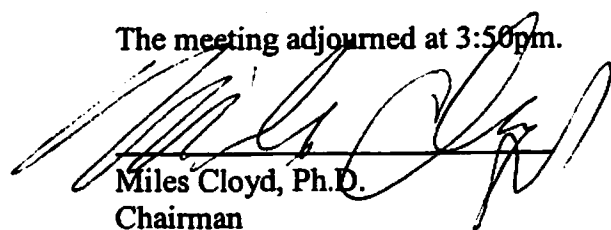
III. OLD BUSINESS

None

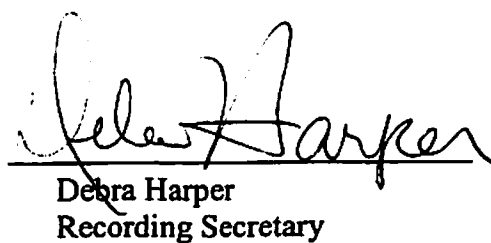
IV. Other Business

Ms. Zimmerman distributed to the Committee members a copy of the NIH Guidelines for Research Involving Recombinant DNA Molecules.

The meeting adjourned at 3:50pm.



Miles Cloyd, Ph.D.
Chairman



Debra Harper
Recording Secretary



THE UNIVERSITY OF TEXAS SYSTEM

Office of the Chancellor

601 COLORADO STREET AUSTIN, TEXAS 78701-2982

University of Texas System

Office of Health Affairs

601 Colorado Street

Austin, Texas 78701

Telephone (512) 499-4224 Fax (512) 499-4313

Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston

MINUTES

November 4, 2005

The Institutional BioSafety Committee met on Friday, November 4, 2005 call to order at 2:00PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nelson Avery, M.D.

Allan Barrett, Ph.D.

Nigel Borne, Ph.D.

Miles Cloyd, Ph.D.

Tonyia Eaves-Pyles, Ph.D.

Amy Goebel

Miguel Grimaldo

Juan P. Olano, M.D.

Wayne Patterson, Ph.D.

Norbert Roberts, M.D.

Bruce Schoenbucher, ISO

Karen Vargas, DVM

Douglas Watts, Ph.D.

Scott Weaver, Ph.D.

Dana Wiltz-Beckham, DVM

Thomas Wood, Ph.D.

GUEST

Jim Stone

Sophie Carrara-Brocard, Ph.D.

Jet Newton

MEMBERS ABSENT

Robin Brinkmeyer, Ph.D.

Jim Ditty, Ph.D.

Peggy Mann, M.S., M.T.

Johnny W. Peterson, Ph.D.

Jeffrey Rabek, Ph.D.

Kenneth I. Shine, M.D.

Claudio Soto, Ph.D.

Present Ex-Officio-Non-voting

Dee Zimmerman

Absent Ex-Officio-Non-voting

Chris Johnsen

I. APPROVAL OF MINUTES

The minutes of the October 7, 2005 meeting were approved.

II. NEW BUSINESS

Ms. Zimmerman introduced new Committee members, Dr. Barrett and Miguel Grimaldo, Deputy Director for Institutional BioContainment Research. The Committee members were all introduced.

Sanjeev Choudhary, submitted a new NOU for *Respiratory Syncytial Virus (RSV)*.

The Committee approved the NOU with the following requested conditions:

- Only approve for in-vitro usage
- IACUC approved is needed for animal work
- Clarify if you will be the only PI working on this project

Roberto P. Garofalo, M.D., submitted a renewal NOU for *Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV)*. The Committee approved the request with no conditions.

E. Brad Thompson, M.D. submitted a renewal for *Adeno, Lenti and Sindbis viruses*.

The Committee tabled the NOU and requested the following:

- Provide a more detailed description on how the Sindbis virus will be used
- IACUC Hazardous Agent form must be submitted for Adeno, Lenti and Sindbis virus
- Provide description of experience with Adeno, Lenti and Sindbis virus or like viruses at BioSafety Level 2 for laboratory staff listed in NOU
- Provide description for mechanism of laboratory transmission

Jiaren Sun, M.D., Ph.D. submitted an new NOU for *Hepatitis C virus, Vaccinia and Adenovirus carrying HCV C, E₁, E₂ genes*.

The Committee approved the request with the following conditions:

- Add Dr. Lemon to NOU if involved in studies
- Flu vaccination recommended, please contact Employee Health Center

Sanjiv Sur, Ph.D. submitted an NOU renewal for *Ancylostoma ceylanicum, Necator americanus*.

The Committee tabled the NOU and requested the following:

- Provide description of experience for BioSafety Level 2 pathogens
- Complete question #7 – What systems are you using to propagate or study the agent(s) listed above?
- Provide Biosafety cabinet location
- Provide procurement source of biological agents

Stephen Higgs, Ph.D. submitted an NOU renewal for *Dengue viruses (all serotypes and strains), Sindbis virus (all strains, infectious clones, replicons and chimeric viruses), LaCross virus, O'nyong nyong (all strains, infectious clones and chimeras).*

The Committee approved the request with the following conditions:

- Provide IACUC Hazardous Agent form
- Provide experience for personnel of laboratory

Stephen Higgs, Ph.D. submitted an NOU renewal for *Japanese encephalitis virus (all strains, infectious clones and chimeric viruses) (BSL3.)*

The Committee approved the requests with the following conditions:

- Provide IACUC Hazardous Agent Form
- Provide experience for personnel of laboratory
- Provide the Biological Safety Cabinet room location
- Research may not commence without CDC/USDA approval
- Risk Assessment #7 (h) Should state yes, JEV is recommended

Stephen Higgs, Ph.D. submitted an NOU renewal for *Yellow febreriviruses (all strains, infectious clones and chimeric viruses- including substitution of genes from BSL2-dengue viruses; West Niles virus (all strains and replicons); St. Louis encephalitis virus (all strains); Chikungunya virus (all strains, infectious clones and chimeras – including from BSL2-alphaviruses 3.g. O'nyong nyong)*

The Committee approved the request with the following conditions.

- Provide personnel experience
- Provide IACUC Hazardous Agent form
- Remove ECL
- Provide an expanded description of project for listed agents

Concepcion Diaz-Arrastia Green, M.D. submitted a new NOU for *Human papillomavirus.*

Based on the description of the submitted research project HPV is not being isolated for viral manipulation. The scope of project is addressed in the approved NOU for human products. The Committee thanked Dr. Green for the submission but notes that a separate NOU is not required.

Mohammad Jamaluddin, Ph.D., submitted an NOU renewal for *Respiratory Syncytial Virus (RSV), A549, Hep-2, HepG2, HeaS3 cells.*

The Committee approved the NOU with the following clarification:

- Clarify if there are any other personnel working on this project, and if so please provide a name and description of experience.

Luis A. Martinez, Ph.D. submitted a new NOU for *pBabe retroviral vector*.

The Committee approved the NOU with the following clarification:

- Clarify if any other personnel will be working on this project; if so please provide names and description of experience.

Geoffrey T. Swanson, Ph.D. submitted a new NOU for *Lentiviral plasmids*. The Committee approved the request with no conditions.

Helen Hellmich, Ph.D. submitted a new NOU for *Adeno virus, HEK 293 cells*.

The Committee tabled the NOU and requested the following:

- Expand description of project to include methodology
- IACUC approval required prior to commencement of work
- Clarify experience and training for personnel
- Submission of IACUC Hazardous Agent form to the IBC is required

The following NOU for Human Products were approved administratively:

Louise Prakash, Ph.D. was approved for cell cultures.

Satya Prakash, Ph.D., was approved for cell cultures.

Concepcion Diaz-Arrastia Green, M.D., was approved for tissue/bone, blood, serum, body fluids.

N.K. Wills, Ph.D. was approved for cell cultures.

Zhihua Zou, Ph.D., was approved with conditions that all personnel handling all lines get Blood Born Pathogen training and hepatitis B vaccine is recommended.

Anthony O. Okorodudu Ph.D. was approved for blood, serum, body fluids and cell cultures.

Tor Savidge Ph.D. was approved with a condition that Universal Precautions certificate be submitted.

Rinat Esenallev, Ph.D., was approved for cell cultures.

Wolfgang Maret, Ph.D. was approved for cell cultures.

Raymond Flick, Ph.D. requested Dr. Sven Enterlein to be added to existing BSL2 and BSL4 NOU's. The Committee approved the request for in-vitro work only and clarify the experience.

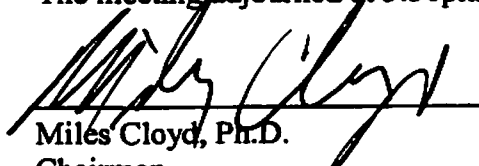
III. OLD BUSINESS

None

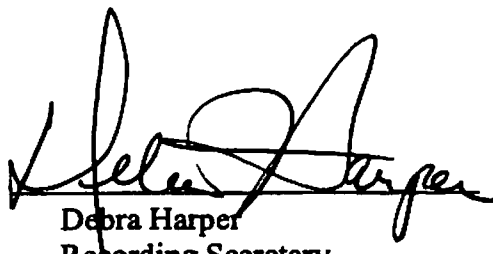
IV. Other Business

Ms. Zimmerman reported that NIH has put together the group National Science Advisory Board for BioSecurity (NSABB). The NSABB is established to provide advice to the federal government departments and agencies on how to minimize knowledge and technologies from vital important biological research. The NSABB has up to 25 voting members. The NSABB meets to discuss the role of the Institutional BioSafety Committee's and to establish guidelines on handling scientific research. Dr. Stan Lemon is a member of the Committee. Ms. Zimmerman would like to invite Dr. Lemon to attend our Institutional BioSafety Committee meetings to provide information from their discussions.

The meeting adjourned at 3:30pm.



Miles Cloyd, Ph.D.
Chairman



Debra Harper
Recording Secretary



University of Texas System
Office of Health Affairs
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
October 7, 2005**

The Institutional BioSafety Committee met on Friday, October 7, 2005 call to order at 2:00PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nelson Avery, M.D.
Nigel Borne, Ph.D.
Miles Cloyd, Ph.D.
Jim Ditty, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Amy Goebel
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Johnny Peterson, Ph.D.
Norbert Roberts, M.D.

Bruce Schoenbucher, ISO
Scott Weaver, Ph.D.
Thomas Wood, Ph.D.

MEMBERS ABSENT

Robin Brinkmeyer, Ph.D.
Wayne Patterson, Ph.D.
Jeffrey Rabek, Ph.D.
Kenneth I. Shine, M.D.
Claudio Soto, Ph.D.
Lee Thompson
Karen Vargas, DVM
Douglas Watts, Ph.D.
Dana Wiltz-Beckam, D.V.M.

Present Ex-Officio-Non-voting

Dee Zimmerman

Absent Ex-Officio-Non-voting

Chris Johnsen

GUEST

Jim Stone
Anne-Sophie Brocard, Ph.D.
Thillai Koothan
Rick Pyles

I. APPROVAL OF MINUTES

The minutes of the September 2, 2005 meeting were approved.

II. NEW BUSINESS

The IACUC requested that the Institutional BioSafety Committee reviews a request from Li-Yen Mae Huang, Ph.D for a change in Animal biosafety level assignment of experiments for work with replication deficient Adeno Associated Virus for the pending sheep protocol #0506030. Dr. Rick Pyles, Vice Chair of the IACUC attended the meeting and to present the request and discussed the issues with the Committee members.

The Committee approved the change with the following conditions:

- Inoculations and recovery be done in Surgical Research permanent housing under ABSL2 conditions.
- Permanent housing be in ARC under ABSL1 conditions.

Amjad Hossain, Ph.D., HCLD submitted an NOU for *clinical application of In-vitro fertilization and culture of human gametes and embryos*.

The Committee approved the NOU for BSL2 work with the following conditions:

- BSL2 signage must be posted
- BSL2 laboratory practices including use of sterile gloves must be followed at all times when handling any human products.

C. J. Peters, M.D., submitted an NOU request to work with the recombinant DNA agents(s) *Rift Valley Fever MP12 Vaccine Virus (RVF MP12)*.

The Committee approved the NOU with the following:

- Clarify the building and room location of the Biological Safety Cabinet.

Pankaj J. Pasricha, M.D. submitted a NOU renewal for *Plasmids, oligonucleotides, siRNA, replication defective Herpes Simplex Virus (HSV), Feline Immunodeficiency Virus (FIV) based pseudovirus, Human Immunodeficiency Virus (HIV) based pseudovirus*.

The Committee approved the requested the following conditions:

- Describe how the Herpes Simplex Virus (HSV) is replication defective.
- Expand information on personnel experience.

Slobodan Paessler, M.V.D., Ph.D. submitted an NOU for *Hemorrhagic fever viruses belonging to the virus family Arenaviridae –Lassa, Junin, Machupo, Guanarito and Sabia viruses*.

The NOU was approved with no conditions. Dr. Weaver abstained.

Slobodan Paessler, M.V.D., Ph.D. submitted an NOU for *Influenza A Viruses*.

The Committee approved the request with the following conditions:

- Resubmit only BSL4 work for this protocol
- Provide experience in handling ferret like animals
- Flu vaccination recommended

Dr. Weaver abstained.

Slobodan Paessler, M.V.D., Ph.D. submitted an NOU for *Influenza A (H3N2 like strains)*. The Committee approved the request with the following condition:

- Flu vaccination recommended

Dr. Weaver abstained.

Tor C. Savidge, Ph.D., submitted an NOU for *Plasmid and cDNA from plants*. The NOU was tabled. The Committee would like an expanded description of this protocol to include methodology of the project.

Lynn Soong, Ph.D. submitted an NOU renewal for *Non-Pathogenic E. coli, Leishmania parasite*. The Committee approved the request with the following condition:

- Provide description of in-vivo experience

Philip R. Wyde, Ph.D., submitted an NOU for *SARS-corona virus*. The Committee approved the request with the following condition:

- Must shower out with animal work

Dragolsava Zivadinovic submitted an NOU for *E.coli DH5 alpha; E. coli BL21 (DE3)*. The Committee approved the request with no conditions.

The following NOU for Human Products were approved administratively:

Elsa Bello-Reuss, M.D, was approved for tissue/bone, cell cultures.

Tonyia Eaves-Pyles, Ph.D., was approved for blood, serum, body fluids.

William J. Calhoun, M.D., was approved for blood, serum, body fluids.

Rolf Konig, Ph.D., was approved for tissue/bone and cell cultures.

Pankaj J. Pasricha, M.D., was approved for tissue, bone, blood, serum, body fluids and cell cultures.

J. Regino Perez-Polo, Ph.D., was approved for tissue/bone, cell cultures.

Ping Wu, Ph.D., was approved for cell cultures.

Dragoslava Zivadinovic, Ph.D., was approved for cell cultures.

Amarnath Natarajan, Ph.D., was approved for cell cultures.

Karl E. Anderson, M.D., and Chul Lee, Ph.D. were approved for blood, serum, body fluids.

Fujio Suzuki, Ph.D., was approved for cell cultures.

III. OLD BUSINESS

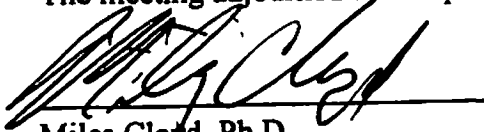
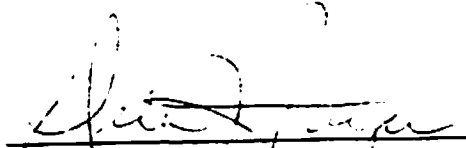
None

IV. Other Business

Ms. Zimmerman mentioned that copies of the BSL4 manual and SOP's will be brought to the next Committee meeting.

Ms. Goebel announced that at the next Institutional BioSafety Committee meeting the Info-Ed process may be introduced. The Info-Ed process is an on-line support that IACUC and IRB are now using for protocols.

The meeting adjourned at 3:45pm.


Miles Cloyd, Ph.D.
Chairman
Debra Harper
Recording Secretary



THE UNIVERSITY OF TEXAS SYSTEM

Office of the Chancellor

601 COLORADO STREET AUSTIN, TEXAS 78701-2982

University of Texas System

Office of Health Affairs

601 Colorado Street

Austin, Texas 78701

Telephone (512) 499-4224 Fax (512) 499-4313

Institutional BioSafety Committee

For the University of Texas Medical Branch at Galveston

MINUTES

September 2, 2005

The Institutional BioSafety Committee met on Friday, September 2, 2005, call to order at 2:10PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nigel Borne, Ph.D.

Robin Brinkmeyer, Ph.D.

Miles Cloyd, Ph.D.

Jim Ditty, Ph.D.

Peggy Mann, M.S., M.T.

Juan P. Olano, M.D.

Johnny Peterson, Ph.D.

Norbert Roberts, M.D.

Bruce Schoenbucher, ISO

Karen Vargas, DVM

Scott Weaver, Ph.D.

Thomas Wood, Ph.D.

MEMBERS ABSENT

Tonyia Eaves-Pyles, Ph.D.

Nelson Avery, M.D.

Amy Goebel

Wayne Patterson, Ph.D.

Jeffrey P. Rabek, Ph.D.

Kenneth I. Shine, M.D.

Claudio Soto, Ph.D.

Lee Thompson

Present Ex-Officio-Non-voting

Dee Zimmerman

Absent Ex-Officio-Non-voting

Chris Johnsen

GUEST

Jim Stone

Anne-Sophie Brocard, Ph.D.

I. APPROVAL OF MINUTES

The minutes of the August 5, 2005 meeting were approved. Dr. Cloyd abstained.

II. NEW BUSINESS

Vladimir Motin, Ph.D. submitted an NOU for use of biological agents Recombinant DNA for Exempt strains of Yersinia pestis, control laboratory strains of E. coli and enteropathogenic Yersinia (Y. pseudotuberculosis and Y. enterocolitica) and the rat flea Xenopsylla cheopis. The Committee tabled the NOU.

The Committee requested the following:

- Provide Standard Operating Procedures (SOP's) for colony maintained
- Provide description to Section II, question 2.e) How do you know inserted genes do not change virulent path/host?
- Provide detailed documentation from Dr. Ken Gage with CDC regarding Jennilee Robinson's training and ability to work independently.
- Provide information regarding the ability of the flea to survive off the host and is there a possible alternate host, if preferred host not present.
- Provide location from Dr. Higgs regarding housing of animal used to maintain colony.
- How are fleas accounted for after manipulation?
- How will you assure all fleas have been removed from the host animal?
- How will you keep fleas from infesting other animals housed in same location?

The Committee requested that Dr. Motin, Ms. Robinson and Dr. Higgs attend the next Committee meeting to provide information as needed.

Jeffrey D. Cecil, Ph.D. submitted a blanket NOU to the Committee for rDNA constructs DNA mouse embryonic stem cells for the transgenic mouse facility. The Committee approved the NOU blanket. Discussion followed. Ms. Zimmerman mentioned that at a meeting held by NIH, Office of BioTechnology regarding the Institutional BioSafety Committee a topic of discussion was experiments involving the generation of transgenic rodents. Although work with the transgenic animals at biosafety level 1 and does not require IBC review and approval it does require that a letter of notification be sent to the IBC when a transgenic animal is created.

III. OLD BUSINESS

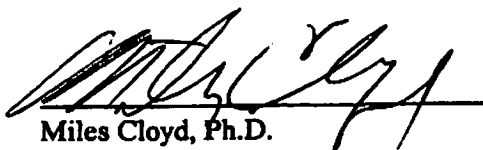
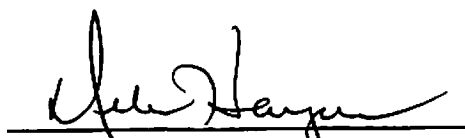
Response to Conditions:

Dr. Ping Wu provided the responses as requested to the Committee.

Dr. Melissa Wentz provided responses to the Committee. The Committee requested that the number of years of experience is needed for Sana Salih, M.D. Also provide information as to what they did with the animals.

IV. Other Business

Ms. Zimmerman reported that the NIH Office of Biotechnology is in the process of reviewing the current NIH guidelines with the intent of enhancing national oversight of dual use life sciences research. To that end the National Science Advisory Board of Biosecurity (NSABB) was created to develop criteria for national policy for conduct of dual use research that would be considered experiments of concern. The Committee has 25 voting members that were appointed by the Secretary of Health and Human Services. The role of the IBC may be directed towards actual evaluation of the ethics of "dual use" scientific projects. NSABB has discussed the feasibility of this review to be done at the individual IBC level rather than reverting to the original RAC review process. Dr. Stanley Lemon is a member of the NSABB committee and will be invited to discuss some of the topics that are presented at these meetings.


Miles Cloyd, Ph.D.
Chairman
Debra Harper
Recording Secretary



THE UNIVERSITY OF TEXAS SYSTEM

Office of the Chancellor

601 COLORADO STREET AUSTIN, TEXAS 78701-2982

University of Texas System

Office of Health Affairs

601 Colorado Street

Austin, Texas 78701

Telephone (512) 499-4224 Fax (512) 499-4313

Institutional BioSafety Committee

For the University of Texas Medical Branch at Galveston

MINUTES

August 5, 2005

The Institutional BioSafety Committee met on Friday, August 5, 2005, call to order at 2:05PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Weaver chaired the meeting.

MEMBERS PRESENT

Jim Ditty, Ph.D.

Tonyia Eaves-Pyles, Ph.D.

Peggy Mann, M.S., M.T.

Juan P. Olano, M.D.

Johnny W. Peterson, Ph.D.

Jeffrey P. Rabek, Ph.D.

Norbert Roberts, M.D.

Bruce Schoenbucher, ISO

Claudio Soto, Ph.D.

Karen Vargas, DVM

Douglas Watts, Ph.D.

Scott Weaver, Ph.D.

Dana Wiltz-Beckam, D.V.M.

Thomas Wood, Ph.D.

MEMBERS ABSENT

Nelson Avery, M.D.

Nigel Bourne, Ph.D.

Robin Brinkmeyer, Ph.D.

Miles Cloyd, Ph.D.

Amy Goebel

Wayne Patterson, Ph.D.

Kenneth I. Shine, M.D.

Lee Thompson

Present Ex-Officio-Non-voting

Dee Zimmerman

Absent Ex-Officio-Non-voting

Chris Johnsen

GUEST

Jim Stone

Anne-Sophie Brocard, Ph.D.

Jet Newton

I. APPROVAL OF MINUTES

The minutes of the July 8, 2005 meeting were approved with changes.

II. NEW BUSINESS

Ping Wu, M.D., Ph.D. submitted an NOU for use of Recombinant adeno-associated virus vector.

The NOU was approved with the following conditions:

- Clarification of the infectious DNA/RNA be used in tissue culture.
- Expand information on "virus-free helper system" and is there a possibility of generating live virus.
- Must have IACUC approval for BSL2 animal work.

Melissa J. Wentz, Ph.D. submitted an NOU for use of Replication-incompetent adenovirus type 5 vectors.

The NOU was approved with the following conditions:

- Provide personnel documentation of experience and training with animals
- Provide room location of the Biological safety cabinet number
- Ayman Al-Hendy, M.D., Ph.D. is approved for in-vitro use only

Tonyia Eaves-Pyles, Ph.D. submitted an NOU for use of Francisella tularensis strain Schu 4 in the BSL 3. The Committee approved the request with clarifications of the role of blood and urine in transmission of Francisella tularensis since question 8 and 9 contradict each other and the MSDS states that blood, urine, and tissue are modes of transmission as stated in the response to question 8. Dr. Eaves-Pyles and Dr. Peterson abstained.

Ashok K. Chopra, Ph.D. submitted a request for an addition of personnel to an approved NOU. The Committee approved the request. Dr. Eaves-Pyles and Dr. Peterson abstained.

George H. Greeley, Ph.D. submitted an NOU renewal request. The Committee discussed the NOU and decided that this NOU does not need Committee approval since the work will be done by Dr. Ceci in his laboratory. IACUC approval is required to work with the generated animals and breeding. The Committee wanted to know if Dr Ceci's NOU was a "blanket" one to generate any type of transgenic mice. Ms Zimmerman indicated that she will look into the matter.

III. OLD BUSINESS

Response to Conditions – None

The NOU Status Summary for Human Products was approved administratively in July.

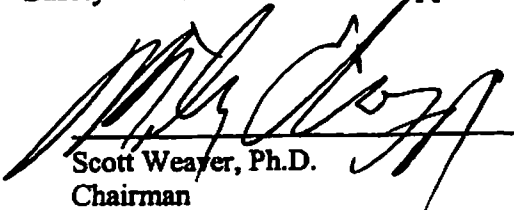
IV. Other Business

Ms. Zimmerman provided the Institutional BioSafety Committee meeting dates for September 2005 – August 2006. The meetings will be held in the same location at Marie Hall. New members will be appointed to the Committee.

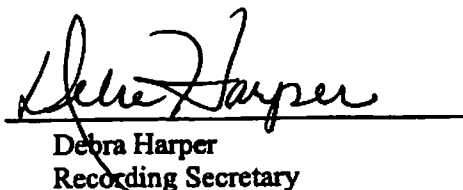
Ms. Zimmerman provided the updated Policy and Procedures Manual for the Institutional BioSafety Committee members. The Meeting Procedure states that a quorum will be 50 percent of the total membership.

Ms. Zimmerman mentioned that Environmental Health & Safety is now providing a "Laboratory BioSafety Training Program". Anne-Sophie Brocard, Ph.D. is providing the training for BioSafety Level III (BSL 3). Dr. Brocard gave a brief overview of the programs content and hands on training for access to the BSL 3 facilities on campus.

Ms. Zimmerman provided an article to the Committee "The Rational Investigation into Safety and Containment As Applied in the Laboratory Environment".



Scott Weayer, Ph.D.
Chairman



Debra Harper
Recording Secretary



THE UNIVERSITY OF TEXAS SYSTEM

Office of the Chancellor

601 COLORADO STREET AUSTIN, TEXAS 78701-2982

University of Texas System

Office of Health Affairs

601 Colorado Street

Austin, Texas 78701

Telephone (512) 499-4224 Fax (512) 499-4313

Institutional BioSafety Committee

For the University of Texas Medical Branch at Galveston

MINUTES

July 8, 2005

The Institutional BioSafety Committee met on Friday, July 8, 2005, call to order at 2:05PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nigel Borne, Ph.D.

Miles Cloyd, Ph.D.

Tonyia Eaves-Pyles, Ph.D.

Amy Goebel

Peggy Mann, M.S., M.T.

Johnny Peterson, Ph.D.

Jeffrey P. Rabek, Ph.D.

Norbert J. Roberts, M.D.

Bruce Schoenbucher

Karen Vargas, D.V.M.

Wayne Patterson, Ph.D.

Dana Wiltz-Beckam, D.V.M.

MEMBERS ABSENT

Nelson Avery, M.D.

Robin Brinkmeyer, Ph.D.

Jim Ditty, Ph.D.

Juan P. Olano, M.D.

Kenneth I. Shine, M.D.

Claudio Soto, Ph.D.

Lee Thompson

Douglas Watts, Ph.D.

Thomas Wood, Ph.D.

Scott Weaver, Ph.D.

Ex-Officio-Non-voting

Chris Johnsen

Dee Zimmerman

Guests

Jim Stone

Sophie Carrara-Brocard

I. APPROVAL OF MINUTES

The minutes of the June 3, 2005 meeting were approved with changes.

II. NEW BUSINESS

Dr. Allan Brasier submitted an NOU for use of E.coli [HB101, JM109, BL21 (DE3), XL1Blue] Class I, non-enteropathogenic; Baculovirus (Class 1).

The NOU was approved for Section I and II with conditional approval for Section III.

The conditions are as follows:

- Clarification of animal work being done, and the agent dosage.
- Provide hazardous agent form.

Dr. Michael Holbrook submitted an NOU for use of Powassan, West Nile, Yellow Fever, and St Louis encephalitis. The NOU was approved with the following conditions:

- Provide a copy of the MSDS sheets.
- Animal work not to proceed without IACUC approval.

Dr. Michael Holbrook submitted an NOU for use of Japanese encephalitis. The NOU was approved with the following conditions:

- Provide a copy of the MSDS sheets
- Animal work not to proceed without IACUC approval.

III. OLD BUSINESS

Dr. Vladimir Motin responded to the conditions set forth by the committee.

Dr. Joan Nichols responded to the conditions set forth by the committee.

Dr. Norbert Roberts responded to the conditions set forth by the committee.

Dr. D. M. Estes responded to the conditions set forth by the committee.

Request for new staff for NOU's - Approved

Dr. Johnny Peterson requested to add additional new staff members. Dr. Peterson abstained.

Dr. Ashok Chopra requested to add additional new staff members.

BSL-3 Access request for the following PI's - Approved

Je'Taime Newton – Dr. Donald Bouyer

Request for Immunizations – Approved

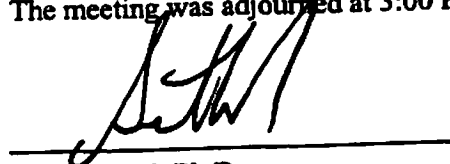
None

Ms. Zimmerman provided articles to the Committee "Researcher alleges CDC cover-up and CDC report author contradicts findings".


Ms. Zimmerman reminded the Committee that the reappointment letters to the IBC Committee would be forth coming.

Ms. Zimmerman reported to the Committee an event that occurred in the BioSafety Level 4 Laboratory (BSL4). During the annual maintenance shutdown there was a mechanical failure occurred to the laboratory doors. The magnets controlling two of the doors within the lab de-energized the magnetic doors locks and the doors briefly unlocked. The door from the buffer corridor into the fumigation room opened slightly. The door was closed and the magnetic lock immediately engaged. The lab contained no viable pathogens at the time of the event. Live agent was last used on May 19, 2005. The University notified members of the UTMB Community Advisory Committee of the event. UTMB University Advancement notified the Galveston Daily News. Public notification maintains the commitment made by both Dr. Stobo and Dr. Lemon for open community dialogue. Research into the cause of the malfunction is progressing and will result in a final report to be presented to Dr. Lemon.

The meeting was adjourned at 3:00 PM.



Miles Cloyd, Ph.D.
Chairman



Debra Harper
Recording Secretary

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Office of Health Affairs
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
June 3, 2005**

The Institutional BioSafety Committee met on Friday, June 3, 2005, call to order at 2:50 PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Wayne Patterson chaired the meeting.

MEMBERS PRESENT

Norbert Roberts, M.D.
Peggy Mann, M.S., M.T.
Thomas Wood, Ph.D.
Amy Goebel, CIH
Johnny W. Peterson, Ph.D.
Jeffrey P. Rabek, Ph.D.
Miles Cloyd, Ph.D.
Robin Brinkmeyer, Ph.D.

Douglas Watts, Ph.D.
Karen Vargas, D.V.M.
Bruce Schoenbucher
Wayne Patterson, Ph.D.

MEMBERS ABSENT

Nelson Avery, M.D.
Dr. Kenneth I. Shine, M.D.
Lee Thompson
Dana Wiltz-Becham, DVM
Nigel Bourne, Ph.D.
Jim Ditty, Ph.D.
Chris Johnsen (Ex officio non voting)
Dee Zimmerman (Ex officio non voting)

GUEST

Ex-Officio-Non-voting

I. APPROVAL OF MINUTES

The minutes of the May 6, 2005 meeting were approved with changes.

II. NEW BUSINESS

Dr. Estes submitted an NOU for use of Adenovirus containing construct for FMDV capsid antigens. The Committee discussed yellow bag and red bag waste procedures, it was noted that all waste to be incinerated now should be placed in yellow bags, all animal carcasses are to be taken by ARC personnel to the incinerator, and red bag waste will be autoclaved and macerated.

The NOU was approved with the following conditions:

- Please provide PI lab experience.
- Please provide location of Biosafety cabinet.

Dr. Hall submitted an NOU for use of Uropathogenic *E. coli*, the committee did make a comment that caviicide would be an acceptable surface decontaminant and spill cleaning agent.

The NOU was approved with no conditions.

Request for Immunization

Dr. William Witt – Nick Christopher Copper – Yellow Fever-Japanese Encephalitis/Smallpox

Dr. D. M. Estes – D M Estes – Yellow Fever

Dr. Becky Langer-Curry – Shannon Sobkowiak – Yellow Fever

Dr. Robert B. Tesh – Olivia K Donan – Yellow Fever

Shd not
have
released

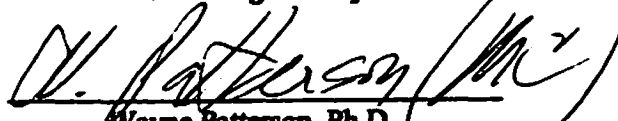
III. OLD BUSINESS

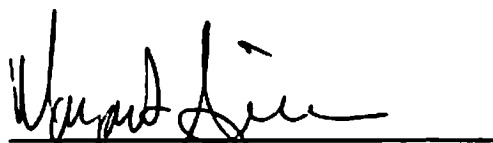
Dr. Vladimir Motin responded to the conditions set forth by the committee.

Dr. Rebecca C. Langer-Curry responded to the conditions set forth by the committee.

Dr. Mike Holbrook responded to the conditions set forth by the committee.

The meeting was adjourned at 3:25 PM.


Wayne Patterson, Ph.D.
Chairman


Margaret Gibbons
Recording Secretary

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Office of Health Affairs
601 Colorado Street
Austin, Texas 78701
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**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
May 6, 2005**

The Institutional BioSafety Committee met on Friday, May 6, 2005, call to order at 2:05PM in the Marie Hall Room, School of Allied Health/School of Nursing. Dr Miles Cloyd chaired the meeting.

MEMBERS PRESENT

Norbert Roberts, M.D.
Peggy Mann, M.S., M.T.
Thomas Wood, Ph.D.
Amy Goebel, CIH
Johnny W. Peterson, Ph.D.
Jeffrey P. Rabek, Ph.D.
Miles Cloyd, Ph.D.
Robin Brinkmeyer, Ph.D.

Douglas Watts, Ph.D.
Karen Vargas, D.V.M.

MEMBERS ABSENT

Nelson Avery, M.D.
Dr. Kenneth I. Shine, M.D.
Lee Thompson
Wayne Patterson, Ph.D.
Dana Wiltz-Becham, DVM
Nigel Bourne, PhD
Jim Ditty, PhD
Juan Olano, PhD
Claudio Soto, PhD
Bruce Schoenbucher
Scott Weaver, Ph.D.
Chris Johnsen (Ex officio non voting)

GUEST

Ex-Officio-Non-voting
Dee Zimmerman

I. APPROVAL OF MINUTES

The minutes of the April 1, 2005 meeting were approved as submitted.

II. NEW BUSINESS

Dr Tanvir Bell submitted an NOU for MRK Ad5 HIV-1 GAG Vaccine that will be used in a phase two human clinical trial. NIH requested submission of the vaccine protocol to the IBC for approval. The submission included the NOU for rDNA and the UTMB Human Gene Therapy submission. The human use protocol has been reviewed by the UTMB Institutional

Review Board and approved with conditions. The NOU included pharmaceutical review of the OBA review of the vaccine protocols. The vaccine is be used to augment the ability of the human immune system to fight HIV infection. The Committee noted that the vaccine will be manufactured and received in ready to use form. There was discussion regarding clinician experience with the vaccine and the possibility of infection if are not properly trained. The Committee noted that the experience and training level of clinical staff included the accepted application of Standard/Universal precautions that are fundamental to the healthcare setting. It was also noted that all clinical staff receive annual blood borne pathogen and Standard/Universal precautions training.

The NOU was approved with no conditions.

Dr. Rebecca C Langer-Curry submitted an NOU for the use of Mengo Virus. Need expanded description of virus. Need more information on virus experience included with description of experience.

The NOU was approved with the following conditions:

- Expand experience to include virus work.
- Animal work not to proceed without IACUC approval.
- Provide location of biosafety cabinet.
- Answer to question 10 must include lab coat.

Dr. Vladimir L Motin submitted an NOU for the use of Bartonella species: E coli clones expressing virulence and housekeeping genes of *Bartonella* spp.; Vero E6 cell line. The Committee requested additional information describing UTMB lab experience. The Committee discussed possible routes for infection, and appropriate sterilization procedures.

The NOU was approved with the following conditions:

- Answer to question 5 must include possibility of potential laboratory exposure. Please provide routes of laboratory exposure.

Dr. D. Mark Estes submitted an NOU for the use of *Burkholderia mallei*. The rDNA section was not completed since no rDNA work is being done at this time. The Institutional Animal Care and Use protocol review is pending.

The NOU was approved with the following conditions:

- A NOU for rDNA work must be submitted prior to commencement of rDNA research.
- Animal work not to proceed without IACUC approval.
- BSL3 documentation of completed training must be submitted to the Committee.
- Work shall not begin until CDC Select Agent approval has been received.

Dr Rebecca C Langer-Curry submitted an NOU for the use of West Nile Virus. The committee noted that she has been working with Dr Tesh and may have experience at BSL3. Additional information regarding BSL3 training to include the viruses should be included in the description of experience.

The NOU was approved with the following conditions:

- Expand experience to include virus work. BSL3 documentation of training must be submitted to the Committee.
- Animal work not to proceed without IACUC approval.
- Provide location of biosafety cabinet.

Dr Michael Holbrook submitted an NOU for the use of Omsk hemorrhagic fever virus, Kyasanur Forest disease virus, Tick borne encephalitis viruses (Western, Siberian, Far eastern subtypes including Russian spring-summer encephalitis). Dr Holbrook has been a co-investigator with Dr Barrett previously, and is requesting to be a principal investigator. The IACUC animal protocol is pending review in the next IACUC next study session. The committee discussed the need for TBE vaccination for BSL3 and BSL4 work. Dr. Holbrook will be asked to clarify the use of immunization as it pertains to his research project.

The NOU was approved with the following conditions:

- Must have IACUC approval prior to animal work.
- Provide clarification on immunization procedures.

Drs. Ramon Flick and Slobodan Paessler submitted an NOU for the use of Crimean Congo hemorrhagic fever virus in animals. The proposed animal work is in conjunction with the approved *in vitro* CCHF NOU. Committee felt that description of agent stability in the risk assessment is misleading would like to request additional information to clarify the statement in the submission. The Committee noted a discrepancy in the listed dose for PBS solution and would like confirmation that the dose is not 20 mls. The IACUC protocol is pending final approval.

The NOU was approved with the following conditions:

- Clarify answer on agent stability.
- Animal work not to proceed without IACUC approval.
- Correct description of use to indicate the correct dose of PBS to be administered to animals into the left-brain hemisphere.

Completed BSL 3 Training

- Heather McSharry

Completed BSL 4 Training

- Slobodan Paessler, DVM, PhD

Request for Immunization

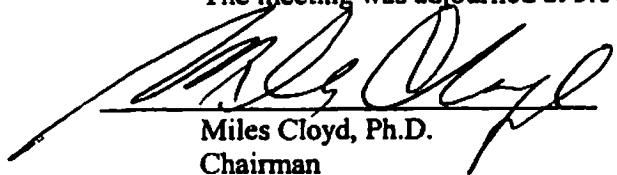
Dr Miles Cloyd – Yan Wang – Yellow Fever
Dr A K Chopra – Tan Lin – Yellow Fever

Revised Notification of Use forms for Biological Agents and rDNA, and BSL3/4 and CDC/USDA Regulated Agents were discussed. A request was made that the committee review and forward comments to EHS Biological and Chemical Safety to compile and amend the forms as needed.

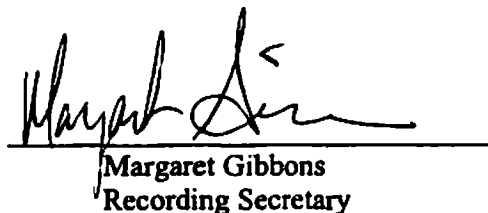
III. OLD BUSINESS

Dr Torres responded to the conditions set forth by the committee.

The meeting was adjourned at 3:07PM.

A handwritten signature in black ink, appearing to read 'Miles Cloyd', written over a horizontal line.

Miles Cloyd, Ph.D.
Chairman

A handwritten signature in black ink, appearing to read 'Margaret Gibbons', written over a horizontal line.

Margaret Gibbons
Recording Secretary

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Office of Health Affairs
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
April 1, 2005**

The Institutional BioSafety Committee met on Friday, April 1, 2005, call to order at 2:06 PM. in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Dana Wiltz-Beckam, D.V.M.
Nigel Bourne, Ph.D.
Jim Ditty, Ph.D.
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Wayne Patterson, Ph.D.
Johnny W. Peterson, Ph.D.
Jeffrey P. Rabek, Ph.D.
Miles Cloyd, Ph.D.
Robin Brinkmeyer, Ph.D.

Bruce Schoenbucher, CSO
Norbert Roberts, M.D.
Claudio Soto, Ph.D.
Karen Vargas, D.V.M.
Scott Weaver, Ph.D.
Thomas Wood, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Amy Goebel, CIH
Douglas Watts, Ph.D.

MEMBERS ABSENT

Nelson Avery, M.D.
Dr. Kenneth I. Shine, M.D.
Lee Thompson

GUEST

Thillai Koothan, D.V.M.
Chris Johnson

Ex-Officio-Non voting

Dee Zimmerman

I. APPROVAL OF MINUTES

The minutes of the March 4, 2005 meeting were approved as submitted.

II. NEW BUSINESS

Dr. Claudio Soto submitted an NOU to work with Creutzfeldt-Jakob Disease (CJD). Included in the NOU was the lab manual for the TSE Laboratory, which has been reviewed and approved by the USDA/APHIS. Proper respiratory protection was discussed, surgical mask was PI choice and agreeable to the committee. Method of disposal for waste options was discussed. Incineration or autoclaving would be appropriate. The option for incineration was a PI choice and agreeable to the Committee.

The NOU was approved with the following condition:

- Clarify work will be done in BSL 2.

- Dr. Claudio Soto submitted an NOU to work with Chronic Wasting Disease (CWD).

The NOU was approved with no conditions.

- Alfredo Torres, Ph.D., submitted an NOU for the use of *Burkholderia mallei* and *B. pseudomallei*, disinfectants listed for surface decontamination and spills was discussed by the committee.

The NOU was approved with the following condition:

- Must complete training for BSL 3.
- C J Peters M.D., submitted an NOU for the use of SARS coronavirus, time limits on pilot project was discussed by the committee. Once pilot project completed, if models are worth follow up, additional protocols will be submitted to continue the experiments.

The NOU was approved only for one pilot project in the ECL, use of the ECL requires submission of the ECL request form and approval of the Chemical Safety Committee.

- Alfredo Torres, Ph.D., submitted an NOU for the use of *Burkholderia mallei* and *B. pseudomallei*.

The NOU was approved with the following condition:

- Please provide location of biosafety cabinet.

BSL3 Provisional Access requests for the following PI's were approved:

- Melissa Worthy – Dr. C. J. Peters
- Mengyi Ye – Dr. David Walker
- Jennilee Robinson – Dr. David Walker

Keiller BSL4 Training Access Request

Dr. John Morrill – Dr. Ramon Flick
Dr. David Walker – Dr Ramon Flick
Dr. John Morrill & Dr. David Beasley

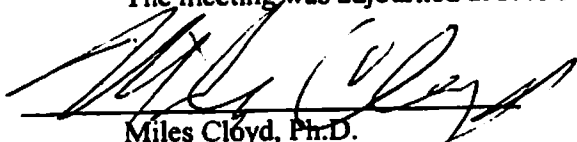
Requests for Immunization - Approved


None

III. OLD BUSINESS

None.

The meeting was adjourned at 3:40 PM.



Miles Cloyd, Ph.D.
Chairman

Margaret Gibbons
Recording Secretary

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**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
March 4, 2005**

The Institutional BioSafety Committee met on Friday, March 4, 2005, call to order at 2:05 PM. in the Marvin Graves building, room 4.208. Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Dana Wiltz-Beckam, D.V.M.
Nigel Bourne, Ph.D.
Jim Ditty, Ph.D.
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Wayne Patterson, Ph.D.
Johnny W. Peterson, Ph.D.
Jeffrey P. Rabek, Ph.D.
Miles Cloyd, Ph.D.

Bruce Schoenbucher, CSO
Norbert Roberts, M.D.
Claudio Soto, Ph.D.
Karen Vargas, D.V.M.
Scott Weaver, Ph.D.
Thomas Wood, Ph.D.
Tonyia Eaves-Pyles, Ph.D.

MEMBERS ABSENT

Nelson Avery, M.D.
Robin Brinkmeyer, Ph.D.
Amy Goebel, CIH
Dr. Kenneth I. Shine, M.D.
Lee Thompson
Douglas Watts, Ph.D.

GUEST

Thillai Koothan, D.V.M

Ex-Officio

Dee Zimmerman
Chris Johnson

I. APPROVAL OF MINUTES

The minutes of the February 4, 2005 meeting were approved as submitted.

II. NEW BUSINESS

- Vivian Braciale submitted an NOU renewal for the use of influenza virus at BioSafety level 2. Duration of use should be changed to five years. There are conflicting answers on agent propagation in the NOU. Need to expand on virus information, and the company they will be obtaining agent from. There was discussion of formatting of the NOU, and

The NOU was approved with the following conditions:

- Summer students should be listed as project personnel if they will be working with the virus, clarify status if they will be added in the future per project description.
- Clarify whether or not virus is to be propagated in lab.
- Answer to question 4 should be 5 years.
- Alfredo Torres, Ph.D., submitted an NOU for the use of *Burkholderia mallei* and *B. pseudomallei*
The NOU was tabled for the following reasons:
Expand lab personnel experience.
Please answer rDNA Section II question 2, description of project.
- Mark Estes, Ph.D., submitted an NOU for the use of *Burkholderia mallei*
The NOU was tabled for the following reasons:
 - Expand on experience for lab personnel and Principle Investigator, identify mentor.
 - Provide more description of use including vaccine candidates and justification for attenuation status.
 - Clarify: there is no information regarding animals, but IP challenge is stated in description of use.
- C J Peters M.D., submitted an NOU for the use of SARS coronavirus
The NOU was tabled for the following reasons:
 - Co-PI must acknowledge responsibility.
 - Provide description of lab experience for all personnel.
 - Define locations of activities of multiple locations are to be considered.
 - Describe method of transmission.
 - Justify need for shower out facilities based on viral load characteristics of animal model.
- Philip Wyde Ph.D., submitted an NOU for the use of SARS coronavirus
The NOU was tabled for the following reasons:
 - Must have UTMB Co-PI that acknowledges responsibility.
 - Please delete all references to Sindbis and submit NOU as SARS only.
 - Expand on experience for lab personnel.
 - Clarify planned location of work including any animal work.
- Alfredo Torres Ph.D., submitted an NOU for use of *Burholderia (Pseudomonas) mallei* and *pseudomallei*
The NOU was tabled for the following reasons:
 - Expand on lab personnel experience.
 - Clarify description to indicate work.
 - Reconcile post exposure treatments on NOU form and MSDA submitted.

BSL3 Provisional Access requests for the following PI's were approved:

Dr. Ramon Flick - Ms. Laura Deflube

Dr. Tonia Eaves-Pyles - Ms. Linsey Anderson

Dr. Clarence J Peters - Dr. Krishna Narayanan

Requests for Immunization - Approved

2 Yellow Fever

1 Japanese encephalitis

1 vaccinia

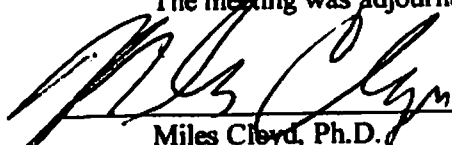
1 influenza

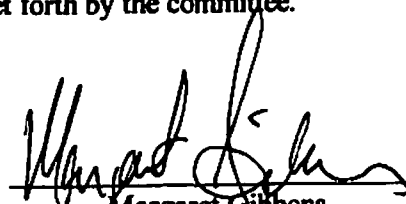
III. OLD BUSINESS

Tasnee Chonmaitree, Ph.D., responded to the conditions set forth by the committee.

Samir Haq, Ph.D., responded to the conditions set forth by the committee.

The meeting was adjourned at 3:00 PM.


Miles Cloyd, Ph.D.
Chairman


Margaret Gibbons
Recording Secretary

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601 Colorado Street
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**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
February 4, 2005**

The Institutional BioSafety Committee met on Friday, February 4, 2005, call to order at 2:05 pm. in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Weaver chaired the meeting.

MEMBERS PRESENT

Dana Wiltz-Beckam, D.V.M.
Nigel Bourne, Ph.D.
Jim Ditty, Ph.D.
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Wayne Patterson, Ph.D.
Johnny W. Peterson, Ph.D.
Jeffrey P. Rabek, Ph.D.

Bruce Schoenbucher, CSO
Norbert Roberts, M.D.
Claudio Soto, Ph.D.
Karen Vargas, D.V.M.
Scott Weaver, Ph.D.
Thomas Wood, Ph.D.
Douglas Watts, Ph.D.

MEMBERS ABSENT

Nelson Avery, M.D.
Robin Brinkmeyer, Ph.D.
Miles Cloyd, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Amy Goebel, CIH
Dr. Kenneth I. Shine, M.D.
Lee Thompson

GUEST

Thillai Koothan, D.V.M

Ex-Officio

Dee Zimmerman
Chris Johnson

I. APPROVAL OF MINUTES

The minutes of the January 7, 2004 meeting were approved as submitted.

II. NEW BUSINESS

Tien Ko, M.D., submitted an NOU for the use of attenuated strains of *E.coli* at BioSafety Level 1. Method of disposal for waste options was discussed. Incineration or autoclaving would be appropriate. The option for incineration was a PI choice and agreeable to the Committee.

The NOU was approved with no conditions.

D.M.Estes, Ph.D., submitted an NOU for the use of Vaccinia virus: Dryvax at BioSafety Level 2. Information on laboratory transmission must be included in the body of the NOU and not just in the IACUC Hazardous Agent form attached. The experience description of staff did not address methods, techniques or length of experience. Institutional Animal Care and Use questions regarding animal housing and the location of the biocabinet the animal facilities will be assigned at time of use since ABSL3 facilities are core facilities. IACUC approval is pending.

The NOU was approved with the following conditions:

- Provide information on lab transmission.
- Expand lab personnel experience to include methods, techniques and length of experience.
- Must receive IACUC approval prior to beginning work.

Chiaho Shih, Ph.D., submitted NOU's for Hepatitis C virus at BioSafety Level 2. The Committee discussed the need to include a better description of the staff experience to include the biosafety level and the laboratory procedures. Even though the NOU instruction has an example for the rDNA table the bacterial strains were not provided.

The NOU was approved with the following conditions:

- Expand on lab experience for Dr. Shih.
- Expand on Biosafety level of lab personnel experience, and what lab procedures personnel have experience with.
- List bacterial strains.
- Request a copy of the IACUC Hazardous agent form.

Chiaho Shih, Ph.D., submitted an NOU for Rift Valley Fever Virus 20MP-12 (attenuated strain) at BioSafety Level 2. Even though the 20MP12 is a vaccine stain it is a BSL2 agent with potential for transmission in the laboratory. Question 4 must be answered yes and transmission information provided. The same conditions for experience and bacterial hosts apply as discussed for the Hepatitis C submission.

The NOU was approved with the following conditions:

- Provide information about susceptibility and transmission of 20MP-12 to humans.
- Additional details on lab personnel experience with virus and cell culture.
- Additional information on bacterial hosts.
- Request a copy of the IACUC Hazardous agent form.

Norbert Roberts, M.D., submitted an NOU for Highly Pathogenic Avian (HPAI) Influenza viruses and reassortant avian-human viruses (to be produced) and MDCK cells containing the gene for α 2-6 sialytransferase.

Dr. Roberts summarized his request and stated that this will involve collaboration with Dr. Robert G. Webster, from St. Jude Children's Research Hospital in Memphis, who is the world's leading expert on avian influenza viruses. Any transfer of material between St. Jude's and UTMB would be coordinated to assure compliance with both CDC and USDA Select Agent regulations. The project has been approved by the initial scientific review committee

and the Steering Committee for the BSL-4 Laboratory. Dr. Roberts is now in the process of obtaining all the necessary CDC/ USDA permits for such work. BSL4 training would commence with Dr. Joan Nichols who is a co-investigator. The Avian influenza viruses are BSL3 plus however since the project involves re-assortants the project is suitable for BSL4. St. Jude's has produced the plasmids and will provide the material for Dr. Roberts. It is a DNA based system done at BSL4. All material leaving the laboratory will be inactivated and tested.

List the bacterial the host cells. Most importantly the inactivation procedures and the methods for verification must be provided with documentation of what is the most sensitive assay available that can be done at BSL4.

The NOU was approved with the following conditions:

- Describe in detail the deactivation procedure and methods for checking deactivation.
- List bacterial host cells.
- Provide documentation of BSL4 training.
- Dr. Nichols will be listed as a Co- Investigator.

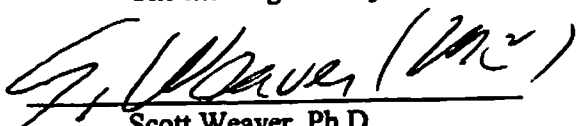
Norbert Roberts M.D., submitted an NOU for use of inactivated materials of pathogenic Avian Influenza viruses and reassortant avian-human viruses at BioSafety Level 2. Verification of inactive will be done before the material is removed from the BSL4 laboratory as state in the BSL4 submission.

The NOU was approved with no conditions.

III. OLD BUSINESS

None

The meeting was adjourned at 4:20 pm.



Scott Weaver, Ph.D.
Co-Chairman



Margaret Gibbons
Recording Secretary



Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
January 7, 2005**

The Institutional BioSafety Committee met on Friday, January 7, 2005, call to order at 3:00 pm. in the Marie Hall Room, School of Allied Health/School of Nursing. Dr. Weaver chaired the meeting.

MEMBERS PRESENT

Nelson Avery, M.D.
Nigel Bourne, Ph.D.
Robin Brinkmeyer, Ph.D.
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Johnny W. Peterson, Ph.D.
Jeffrey P. Rabek, Ph.D.

Norbert Roberts, M.D.
Claudio Soto, Ph.D.
Karen Vargas, D.V.M.
Scott Weaver, Ph.D.
Thomas Wood, Ph.D.
Amy Goebel, CIH
Bruce Schoenbucher, CSO

MEMBERS ABSENT

Miles Cloyd, Ph.D.
Jim Ditty, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Wayne Patterson, Ph.D.
Dr. Kenneth I. Shine, M.D.
Lee Thompson
Douglas Watts, Ph.D.
Dana Wiltz-Becham, D.V.M.

GUEST

JeT'Aime Newton
Jim Stone
Aaron Jones

Ex-Officio

Dee Zimmerman

I. APPROVAL OF MINUTES

The amended minutes of the December 3, 2004 meeting were approved as submitted.

II. NEW BUSINESS

None

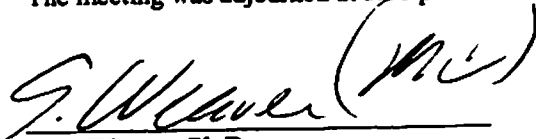
III. OLD BUSINESS

Johnny W. Peterson, Ph.D., submitted a response to the condition for his IACUC protocol and stated that he will provide a printed copy of the IACUC flow chart to the committee at the next meeting.

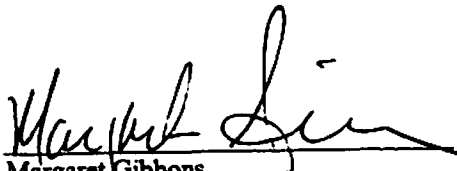
Scott Weaver, Ph.D., submitted an updated list of personnel working on his NOU's for BSL-2 and BSL-3 agents.

Ms. Zimmerman gave an update on the proposed merger of the Institutional BioSafety Committee and Biological Safety Committees, and reported that Chris Johnsen with Legal Services expressed approval. Dr. Wayne Patterson, Institutional Animal Care and Use Committee, was in agreement with the merger and did not feel that the inclusion of animal use protocol would be a deterrent to merging the committees. There was discussion of meeting time being changed to the lunch hour. Members expressed concern that there would be difficulty meeting quorum, thus a motion was made to change the quorum requirements to 50 percent, the motion was passed. A motion was made to merge the Institutional BioSafety Committee and Biological Committees; the motion was passed.

The meeting was adjourned at 3:30 pm.



Scott Weaver, Ph.D.
Co-Chairman



Margaret Gibbons
Recording Secretary



Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
December 3, 2004**

The Institutional BioSafety Committee met on Friday, December 3, 2004, call to order at 2:10 pm. in the Caduceus Room, Administration Building. Dr. Weaver chaired the meeting.

MEMBERS PRESENT

Nigel Bourne, Ph.D.	Bruce Schoenbucher, CSO
Jim Ditty, Ph.D.	Claudio Soto, Ph.D.
Amy Goebel, CIH	Karen Vargas, DVM
Juan P. Olano, M.D.	Norbert J. Roberts Jr., M.D.
Johnny W. Peterson, Ph.D.	Douglas Watts, Ph.D.
Jeffrey P. Rabek, Ph.D.	Scott Weaver, Ph.D.

MEMBERS ABSENT

Nelson Avery, M.D.
Robin Brinkmeyer, Ph.D.
Miles Cloyd, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Peggy Mann, M.S., M.T.
Wayne Patterson, Ph.D.
Kenneth I. Shine, M.D.
Karen Vargas, D.V.M.
Dana Wiltz-Beckam, D.V.M.
Thomas Wood, Ph.D.

GUEST

JeT'Aime Newton
Jim Stone
Thillai Koothan, D.V.M.

Ex-Officio

Dee Zimmerman

I. APPROVAL OF MINUTES

The minutes of the November 5, 2004 meeting were approved as submitted.

II. NEW BUSINESS

Johnny W. Peterson, Ph.D., submitted an rDNA NOU for use of Sindbis virus. The Committee requested that the Institutional Animal Care and Use flow diagram should be submitted to support the animal section.

The rDNA NOU was approved with the following condition:

- Submit the Institutional Animal Care and Use Committee (IACUC) flow diagram

Dr. Peterson abstained.

Ilya V. Frolov, Ph.D., submitted an rDNA NOU for use of the following:

- Recombinant plasmid DNAs containing fragments of M-segment of Rift Valley fever virus genome
- Rift Valley fever virus attenuated strain MP-12
- Recombinant Sindbis virus replicons encoding G2 protein of RVFV and packaged into Sindbis virus structural proteins
- Recombinant Venezuelan equine encephalitis virus TC-83 replicons encoding G2 proteins of RVFV and packaged into VEEV TC-83 structural proteins

Duration of the project cannot exceed 5 years. Human and animal susceptibility to infection for each agent listed was not addressed. Lab room location for the Biocabinet must be provided. Even though the PI is aware of spill procedures it was felt that the step by step procedure needed to be submitted. The Committee decision was to approve with conditions.

The rDNA NOU was approved with the following conditions:

- Complete Section 1 question #5: Are human beings susceptible to infection by this agent?
- Complete Section 1 question #12: Does the infected animal present any health risk after administration?
- Provide the estimated duration of the project
- Provide the biological safety cabinet location
- Provide step by step procedure for spill response

Bogdan J. Nowicki, M.D., Ph.D., submitted a renewal rDNA NOU for use of *Escherichia coli*, *Neisseria gonorrhoeae*, and *Neisseria cinerea*. The NOU only listed *Escherichia coli* as the agent; therefore the other agents listed will be brought back to the Committee for review.

The rDNA NOU was approved for *Escherichia coli* only with the following conditions:

- Provide more information on personnel laboratory experience
- Clarify Section II question #1 question: Does the infected animal present any human health risk after administration?
- Submission did not address *Neisseria gonorrhoeae* or *Neisseria Cinerea*, please submit completed NOUs

Stella Nowicki, DDS, submitted an rDNA NOU for use of *Escherichia coli*, *Neisseria gonorrhoeae*, *Neisseria cinerea*. The NOU did not address either *E.coli* or *N. cinerea*, approved was granted for the *N. gonorrhoeae* with conditions, and a request for submission covering the other two agents.

The rDNA NOU was approved for *Neisseria gonorrhoeae* only with the following conditions:

- Submission did not address *Escherichia coli* or *Neisseria cinerea*, submit completed NOUs
- Clarify Section II question #1: Does the infected animal present any human health risk after administration?
- Provide more information on personnel laboratory experience

Chiaho Shih, Ph.D., submitted an rDNA NOU for use of Human Hepatitis B virus, Hepatitis C virus, Rift Valley Fever Virus, MP-12 strain. The NOU provided a concise description of the HBV work but did not provide sufficient information to support discussion of the proposed use of either HCV or the MP-12 strain of RVFV. Description of the experience for laboratory personal must be expanded to include the number of years experience. The decision was to approve the HBV and not the HCV and RVFV MP-12.


The rDNA NOU was approved for *Hepatitis B virus* only with the following conditions:

- Provide more information on personnel laboratory experience
- Submission did not address RVFV 2MP-12 or Hepatitis C, submit completed NOUs
- Clarify section I question #5: Are human beings susceptible to infection?

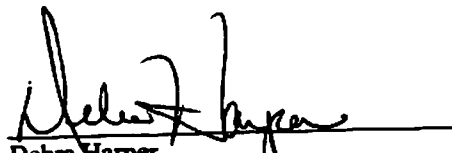
III. OLD BUSINESS

Ms. Zimmerman gave an update on the functions and the separation of the IBC and Biological Safety Committees for the new members of the Committee. Dr. Lemon had expressed that the two Committees be combined back as one Committee under the UT System IBC. The IBC Policy and Procedure Manual outlines the criteria that would be used to redact information from the minutes and NOU's prior to opening the information to the public. The NOUs would be restructured and updated to combine the rDNA with the agent submissions. Members expressed that combining the Committee's would be to our advantage in the streamlining information during review as well as providing the ability to make information available as requested in the NIH rDNA guidelines. Concerns were also expressed regarding the Institutional Animal Care and Use Committee's information in the NOU's. Ms. Zimmerman will contact the IACUC and get feedback. A motion was made to table the discussion until next month's Committee meeting and also to get a letter of recommendation from Chris Johnsen, Legal if not attending the meeting.

The meeting was adjourned at 3:15pm.



Scott Weaver, Ph.D.
Co-Chairman



Debra Harper
Recording Secretary



Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313
Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston
MINUTES
November 5, 2004

The Institutional BioSafety Committee met on Friday, November 5, 2004, call to order at 3:35 pm. in the Marvin Graves Building, Rm. 4.208 Conference Room. Dr. Weaver chaired the meeting.

MEMBERS PRESENT

Nigel Bourne, Ph.D.
Robin Brinkmeyer, Ph.D.
Jim Ditty, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Wayne Patterson, Ph.D.

Johnny W. Peterson, Ph.D.
Norbert J. Roberts Jr., M.D.
Bruce Schoenbucher, CSO
Douglas Watts, Ph.D.
Scott Weaver, Ph.D.

MEMBERS ABSENT

Nelson Avery, M.D.
Miles Cloyd, Ph.D.
Amy Goebel, CIH
Jeffrey P. Rabek, Ph.D.
Claudio Soto, Ph.D.
Karen Vargas, D.V.M.
Dana Wiltz-Beckam, D.V.M.
Thomas Wood, Ph.D.

GUEST

JeT'Aime Newton
Jim Stone
Thillai Koothan, D.V.M.

Ex-Officio

Dee Zimmerman
Chris Johnsen

I. APPROVAL OF MINUTES

The minutes of the October-1, 2004 meeting were approved as submitted.

II. NEW BUSINESS

Dr. Ramon Flick, Ph.D. submitted a rDNA NOU for use of Modified Vaccinia Virus Ankara (MVA) expressing bacteriophage T7 RNA polymerase (MVA-T7). The rDNA NOU was approved with the following condition:

- Transfer the information to the rDNA NOU format

The Committee discussed and reviewed the information and determined that a completed correct rDNA form must be submitted.

Dr. Scott Weaver, Ph.D., submitted an rDNA NOU for use of Chimeric Sinbis-VEE viruses. The rDNA NOU was approved with the following condition:

- Provide a updated personnel list

The Committee discussed that the Biological Safety cabinet needs to be checked off on # 10 on the rDNA form. Dr. Weaver abstained.

Dr. Peter W. Mason, Ph.D. submitted an Addendum to a current flavivirus rDNA NOU to allow for: 1) production of "cross-packaged" VLPs, 2) use of Venezuelan equine encephalitis virus (TC83 strain) replicons, and 3) use of VLPs in animals at ABSL2. Dr. Mason provided a flow gram for review. The Addendum was approved.

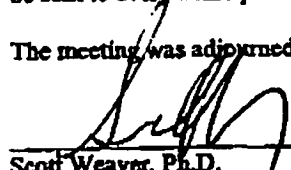
Dr. Yan-Shi Guo, Ph.D. submitted a rDNA renewal for human cell lines: SIIA, HCT 116 and PC-3. A motion was made to table the renewal. Clarification is needed for information to determine if approval is required or are these exempt strains.

III. OLD BUSINESS

The IBC Policy and Procedures Manual will be discussed at the next Committee meeting.

Ms. Dee Zimmerman reported to the Committee that due to some recent research, a State of Texas Health & Safety Code requires that UTMB notify the Galveston County Health District for any shipping or receiving of a communicable disease before it crosses the state line of Texas. The Health District must be notified prior to any shipments shipped as an infectious substance under the Department of Transportation or and International Air and Transportation Association (IATA) regulations. Any infectious substance requiring a dangerous goods manifest must be reported to the Health District. A form will be used to check off and write in the agent and fax or email to the Health District. This is a notification going out under Bruce Schoenbucher, Chief Safety Officer. A letter will be sent to every Principal Investigator, Director, Chairman, Assistant Chairman and Dean on campus.

The meeting was adjourned at 4:00pm.



Scott Weaver, Ph.D.
Co-Chairman



Debra Harper
Recording Secretary



Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
October 1, 2004**

The Institutional BioSafety Committee met on Friday, October 1, 2004, call to order at 1:30 pm. in Conference Room Maric Hall, SAHS Building, Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Nelson Avery, M.D.
Nigel Bourne, Ph.D.
Robin Brinkmeyer, Ph.D.
Miles Cloyd, Ph.D.
Amy Goebel
Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Wayne Patterson, Ph.D.

Jeffrey Rabek, Ph.D.
Norbert J. Roberts, Jr., M.D.
Bruce Schoenbucher, CSO
Claudio Soto, Ph.D.
Douglas Watts, Ph.D.
Scott Weaver, Ph.D.
Dana Wiltz-Beckam, D.V.M.
Thomas Wood, Ph.D.

MEMBERS ABSENT

Jim Ditty, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Johnny Peterson, Ph.D.
Kenneth Shine, M.D.
Lee Thompson
Karen Vargas, D.V.M.

NON MEMBERS PRESENT

Jim Stone

NON MEMBERS ABSENT

Dee Zimmerman
JeT'Aime Newton

I. APPROVAL OF MINUTES

The minutes of the September 3, 2004 meeting were approved with corrections.

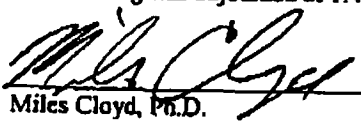
II. NEW BUSINESS

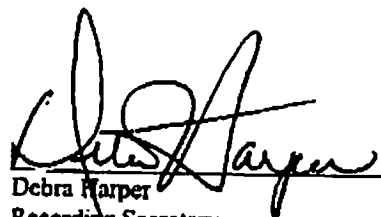
None

III. OLD BUSINESS

None

The meeting was adjourned at 1:40pm.


Miles Cloyd, Ph.D.
Chairman


Debra Harper
Recording Secretary



Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
September 3, 2004**

The Institutional BioSafety Committee met on Friday, September 3, 2004, call to order at 3:30 pm. in Conference Room Marie Hall, SAHS Building, Dr. Cloyd chaired the meeting.

MEMBERS PRESENT

Miles Cloyd, Ph.D.
Jim Ditty, Ph.D.
Amy Gochel
Wayne Patterson, Ph.D.
Johnny W. Peterson, Ph.D.
Norbert Roberts, M.D.
Bruce Schoenbucher, ISO

Claudio Soto, Ph.D.
Karen Vargas, DVM
Scott Weaver, Ph.D.
Thomas Wood, M.D.
Juan Alano, Ph.D.

MEMBERS ABSENT

Nigel Bourne, Ph.D.
Tonyia Eaves-Pyles, Ph.D.
Nelson Avery, M.D.
Peggy Mann, M.S., M.T.
Jeffrey Rabek, Ph.D.
Kenneth I. Shine, M.D.
Lee Thompson
Douglas Watts, Ph.D.

NON MEMBERS PRESENT

Aaron Jones
Jim Stone
Dee Zimmerman
Robin Brinkmeyer, Ph.D.

GUEST

Stanley Lemon, M.D.

I. APPROVAL OF MINUTES

The minutes of the August 6, 2004 meeting were approved with a correction.

II. NEW BUSINESS

Dr. Petri Urvil, Ph.D. submitted an rDNA NOU for use of Escherichia coli, CHO cells. The rDNA NOU was approved.

Dr. Pomila Singh submitted a rDNA NOU for use of strain of E. coli (attenuated strain) retroviral vectors human, mouse and rat cell lines. The rDNA NOU was tabled with the following conditions:

- Provide more information on all four vectors
- Provide a detailed description of training experience for each individual

Dr. Randall Urban submitted a NOU for rDNA for use of BD Adeno-X expression system (pDNR-cmv donor vector and pLP-Adeno-X-cmv Vector), HEK293 packaging cells (both from Invitrogen). The rDNA NOU was approved with the condition:

- Provide a detailed description of training experience for each individual

III. OLD BUSINESS

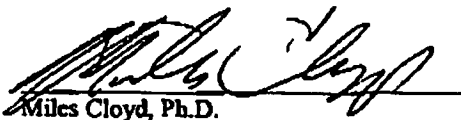
Dr. Shinji Makino submitted an Addendum to an approved NOU. The NOU was approved and the decontamination procedures were provided.

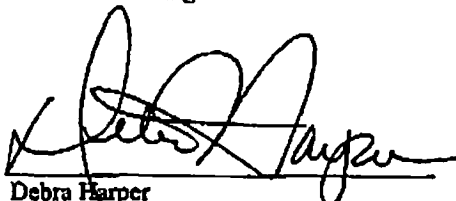
Ms. Zimmerman provided an article for the Committee's review Introduction for "Safety Considerations for Retroviral Vectors: A Short Review".

Ms. Zimmerman introduced Stanley Lemon, M.D., Dean of Medicine to the Committee members. New members were also introduced.

Dr. Lemon attended the meeting since Chris Johnson could not attend. Dr. Lemon gave a brief description of the functions of the Institutional Safety Committee (IBC) and the Biological Safety Committee. Each Institution funded by the NIH to accommodate DNA work would establish a Committee that would oversee within certain federal guidelines the type of rDNA procedures. The NIH guidelines from the rDNA activities the Committee that relates to the IBC require that the minutes of the IBC be available to the public upon request. This is not a NIH requirement only a request. Dr. Lemon suggested and after discussion with Chris Johnson, Legal that the IBC and Biological Safety Committees combine as one UT Systems Committee. There is a recommendation from NIH that certain minutes from the IBC would be open to the public. The minutes of the UT System made available would be redacted under certain guidelines state and federal. The Committee members discussed some concerns and issues. Ms. Zimmerman mentioned that the minutes could be redacted by the Legal Department. Dr. Cloyd mentioned that the minutes should be made available if needed. The Committee will discuss combining both Committees at the next meeting.

The meeting was adjourned at 3:55pm.


Miles Cloyd, Ph.D.
Chairman


Debra Harper
Recording Secretary

Mar 27 06 01:54p UTM8

Dr. Shinji Makino, D.V.M., Ph.D. submitted a rDNA for use of Recombinant plasmid DNAs containing Rift Valley Fever virus (RVFV) vaccine strain MP-12 genome. The rDNA NOU was approved with the following condition:

- Provide step by step procedure for spills

Dr. Jankaj J. Pasriacha, M.D., submitted a rDNA for use of Recombinant, replication defective Herpes Virus. The rDNA NOU was approved.

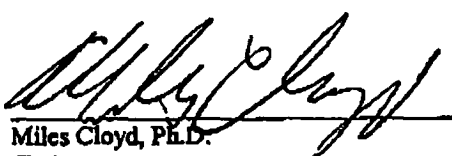
Randall J. Urban, M.D., submitted a rDNA for use of Retrovirus system (pmSCV vector), HEK293 packaging cells (both from Invitrogen). The rDNA NOU was approved.

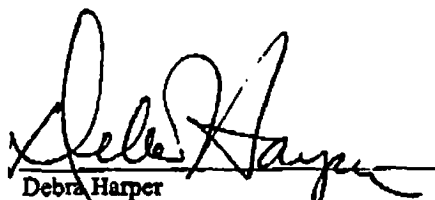
Ms. Zimmerman reported that no comments or changes were received regarding the review of the draft IBC Policies and Procedures Manual. The information will be emailed to Committee members again for any changes or comments.

Chris Johnson, Attorney with Legal Affairs was present to discuss the NIH guidelines requirements for the Institutional BioSafety Committee's. All Committee's should have a Policy & Procedure Manual. Mr. Johnson reviewed the NIH guidelines and requirements that the Committee needs to be charged with accomplishing. The information will guide the Committee in how to handle open record requirements. The Committee discussed combining the IBC and Biological Safety Committee into one Committee.

Ms. Zimmerman reported that a letter was sent to the Office of Biotechnology Activities (OBA) regarding a member of the IBC Committee has relocated and that our office is in the process of a replacement. A letter was sent to Ms. Zimmerman stating that the IBC Committee is now in non-compliance and that an additional community member not affiliated with UTMB curriculum be submitted. The Committee had discussed having at least three members to represent the interest of the community.

The meeting was adjourned at 3:05pm.


Miles Cloyd, Ph.D.
Chairman


Debra Harper
Recording Secretary

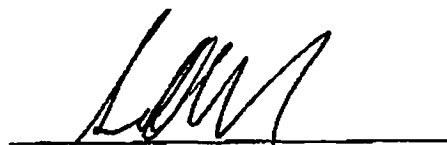
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Dr. Pankaj J. Pasricha, M.D. submitted a rDNA NOU for use of Recombinant replication defective Herpes Virus. The rDNA NOU was tabled until the following is clarified:

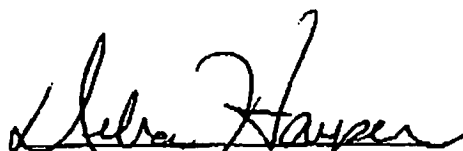
- More details regarding the experience working with the virus.
- Due to conflicting information provided in the submission the Committee requests an explanation of how the Herpes virus is defective.
- Animal work cannot commence until IACUC approval is obtained.

The IBC was requested to review the draft IBC Policies and Procedures Manual and provide any comments or changes prior to the next meeting to be held August 6, 2004.

The meeting was adjourned at 2:42pm.



Scott Weaver, Ph.D.
Chairman



Debra Harper
Recording Secretary

**Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313**

**INSTITUTIONAL BIOSAFETY COMMITTEE
For the University of Texas Medical Branch at Galvesto**

June 4, 2004

**The Institutional BioSafety Committee meeting did not have a quorum for the June meeting. Only discussions.
The information will be brought to the next scheduled meeting.**



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University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

**MINUTES
May 7, 2004**

The Institutional BioSafety Committee met on Friday, May 7, 2004, call to order at 1:35 pm. in Conference Room 2.214 Gail Borden Building, Dr. Wayne Patterson chaired the meeting.

Members Present

Nigel Bourne, Ph.D.	Wayne Patterson, Ph.D.
Chuck Chambers, MPH	Johnny W. Peterson, Ph.D.
Jim Ditty, Ph.D.	Jeffrey Rabek, Ph.D.
Tonyia Eaves-Pyles, Ph.D.	Norbert J. Roberts, Jr., M.D.
Peggy Mann, M.S., M.T	Bruce Schoenbucher, ISO
Juan P. Olano, M.D.	Thomas Wood, Ph.D.

MEMBERS ABSENT

Miles Cloyd, Ph.D.
Amy Goebel, CIH
Kenneth I. Shine, M.D.
Lee Thompson
Karen Vargas, DVM, M.S.
Scott Weaver, Ph.D.

GUEST

Doug Brining, DVM

NON-MEMBERS ABSENT

Jim Stone

NON-MEMBERS PRESENT

Dee Zimmerman
JeT'Aime Newton

I. APPROVAL OF MINUTES

The minutes were approved as submitted.

II. NEW BUSINESS

Rebecca C. Langer, Ph.D., submitted a rDNA NOU for use of *Cryptosporidium*, Caco-2 cells form ATCC to produce cloned DSCAML1 (human protein). The rDNA NOU was approved with conditions. The following conditions: 1) Are human beings susceptible to infection need to state the infection is natural. 2) Clarify Vector E. coli. 3) Clarify if the assay runs through the filter.

C. A. Rijinbrand, Ph.D., submitted a rDNA NOU for use of Sindbis. The rDNA NOU was approved with a condition. The condition is to request the IACUC protocol number, and no animal work can be done until the protocol is approved.

C. A. Rijinbrand, Ph.D., submitted a rDNA NOU for use of Hepatitis C Virus. The rDNA NOU was approved.


C. A. Rijinbrand, Ph.D., submitted a rDNA NOU for use of Human Rhino Virus. The rDNA NOU was approved.

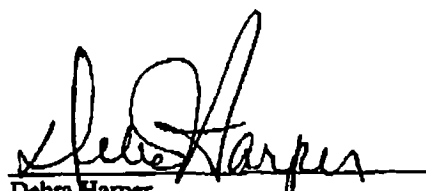
C. A. Rijnbrand, Ph.D., submitted a rDNA NOU for use of GB virus B. The rDNA NOU was approved with a condition. The condition is to clarify the primate cell model.

Ms. Zimmerman discussed the New Biosecurity Initiative information received from Allan Shipp. All the members will be receiving copies of the information by email. As the information is received it may be included in the agenda.

Ms. Zimmerman mentioned that Dr. Skinner, Vice Chair with UT System has been appointed. Dr. Skinner will receive copies of the agenda and may attend the meetings.

The meeting was adjourned at 1:55pm.


Wayne Patterson, Ph.D.
Chaired for Dr. Cloyd


Debra Harper
Recording Secretary

**Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313**

**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

April 2, 2004

The Institutional BioSafety Committee meeting was cancelled due to lack of quorum.

**Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313**

**INSTITUTIONAL BIOSAFETY COMMITTEE
For the University of Texas Medical Branch at Galvesto**

March 5, 2004

The Institutional BioSafety Committee meeting was cancelled due to lack of quorum.



Office of Health Affairs
University of Texas System
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

INSTITUTIONAL BIOSAFETY COMMITTEE
For the University of Texas Medical Branch at Galveston
MINUTES
February 6, 2004

The Institutional BioSafety Committee met on Friday, February 6, 2004, call to order at 1:35 pm. in Conference Room 2.214 Gail Borden Building. Dr. Scott Weaver chaired the meeting.

Members Present

Nigel Bourne, Ph.D.
Chuck Chambers, MPH
Jim Ditty, Ph.D.
Amy Goebel, CIH
Tonyia Eaves-Pyles, Ph.D.
Clarence Jernigan, M.D.

Peggy Mann, M.S., M.T.
Juan P. Olano, M.D.
Johnny W. Peterson, Ph.D.
Jeffrey Rabck, Ph.D.
Bruce Schoenbucher, ISO
Karen Vargas, DVM

Scott Weaver, Ph.D.
Thomas Wood, Ph.D.

MEMBERS ABSENT

Miles Cloyd, Ph.D.
Wayne Patterson, Ph.D.
Norbert J. Roberts, Jr., M.D.
Lee Thompson
James Guckian, MD

NON-MEMBERS ABSENT

Dec Zimmerman
Jim Stone

GUEST

Alan Silva
Ramon Flick
Doug Brining

I. APPROVAL OF MINUTES

The minutes were approved with corrections.

II. NEW BUSINESS


Shinji Makino, Ph.D., submitted a rDNA NOU for use of Recombinant plasmid DNA containing Nipah virus V protein. The rDNA NOU was approved.

Ramon Flick, Ph.D. submitted a rDNA NOU for use of Hantaan virus viral structural and non structural genes and proteins. The rDNA NOU was approved with conditions.

Ramon Flick, Ph.D. submitted an rDNA NOU for use of Lassa, Junin, Machupo, Guanarito, Sabia, Crimean Congo hemorrhagic fever, Ebola, Marburg, KFD, and Omsk rDNA. The rDNA NOU was approved with conditions.

The meeting was adjourned at 1:55pm.


Scott Weaver, Ph.D.
Co-Chairman


Debra Harper
Recording Secretary

**Office of Health Affairs
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**Institutional BioSafety Committee
For the University of Texas Medical Branch at Galveston**

January 2, 2004

The Institutional BioSafety Committee meeting was cancelled due to lack of quorum.

OFFICE OF HEALTH AFFAIRS

The University of Texas System
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Telephone (512) 499-4224 Fax (512) 499-4313

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

December 16, 2003

The Institutional BioSafety Committee met on Tuesday, December 16, 2003, call to order at 1:30 pm. in Conference Room 2.214 Gail Borden Building, Dr. Miles Cloyd chaired the meeting.

Members Present

Miles Cloyd, Ph.D.	Karen Vargas, DVM	Nigel Bourne, Ph.D.
Peggy Mann, M.S., M.T.	Jim Ditty, Ph.D.	Amy Goebel, CIH
Clarence Jernigan, M.D.	Thomas Woods, Ph.D.	Chuck Chambers, MPH
Norbert J. Roberts, Jr., M.D.	Bruce Sheocnbucher, ISO	Wayne Patterson, Ph.D.
Tonyia Eaves-Pyles, Ph.D.		

MEMBERS ABSENT

Juan P. Olano, M.D.
Johnny Peterson, Ph.D.
James Guckian, M.D.

NON-MEMBERS PRESENT

Dee Zimmerman

I. APPROVAL OF MINUTES

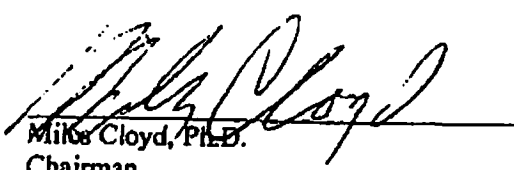
Not applicable

II. NEW BUSINESS

Antonella Casola, M.D. submitted a rDNA NOU for viral-induced gene expression in epithelial cells. The rNOU was approved at BSL2.

Ramon Flick, Ph.D. submitted a rDNA NOU for Uukuniemie, Tula virus and non-pathogenic E.coli for use in molecular cloning. vectors: pcDNA, pdisplay, pCAGGS, and pol1. The rNOU was approved at BSL2.

Ramon Flick, Ph.D. submitted a rDNA NOU for BSL3 and BSL4. The rNOU was tabled for additional information.


Miles Cloyd, Ph.D.
Chairman


Dee Zimmerman
EHS Safety Consultant