

To: "'Johnson, Michelle \(\text{NIH/OD}\) [C]'" <johnsom1@od.nih.gov>
From: Edward Hammond <hammond@sunshine-project.org>
Subject: Re: Response to NIH Complaint
Cc: "Patterson, Amy \(\text{NIH/OD}\) [E]" <PattersA@OD.NIH.GOV>, "Bonham, Valerie \(\text{NIH/OD}\) [E]" <BonhamVa@mail.nih.gov>, "Shipp, Allan \(\text{NIH/OD}\) [E]" <ShippA@OD.NIH.GOV>, "Public Information Requests" <PublicInfo@utsa.edu>, "Julie M Olson" <Julie.Olson@utsa.edu>, "Bennie Keckler" <Bennie.Keckler@utsa.edu>, "Jan Kruse" <Jan.Kruse@utsa.edu>, "David R. Johnson \(\text{Provost Office}\)" <David.Johnson@utsa.edu>

Bcc:

Attachments:

Ms. Johnson-Lancaster:

I have searched my e-mail from April 2006, and UTSA is correct, they informed me on 16 April 2006 that the University was holding its IBC minutes back in exchange for three dollars. I replied that it obviously costing them more than \$3 to collect \$3; but also said that I would pay the ransom. I cannot see, however, that I actually wrote a check. It must have slipped between the cracks.

One might have hoped for a different outcome. First, it can be appreciated that UTSA was prepared to pay many times \$3 in order to collect \$3. Most UT system institutions don't do this; but I guess UTSA has money to burn. The obvious inefficiency argued for release of the minutes sans ransom ... I can't explain the behavior. Also, and again I suppose this is up to UTSA, but Ms. Olsen could have sent me a reminder. After all, I told her that I was going to send the three bucks... the file was, presumably, sitting waiting to be dispatched. A reminder would have avoided the complaint and, ironically, the additional time and effort from senior UTSA officials spent crafting a response to you.

As to the issues about who to contact, this is a rub with many UT institutions. A member of the public cannot be expected to maintain better information on where to request IBC minutes than NIH itself does. I am exercising a right under the Guidelines, not Texas law. Nevertheless, I have found that the enlightened IBCs in the UT system will manage to convey a request sent to the IBC contact (as listed in NIH files) to the right internal UT office for preparation of a response. But there are some laggards, like UTSA, that will refuse to honor a request sent to NIH's own contact for the IBC. UT System is either going to have to address this problem, or NIH will have to collect new data from IBCs on the contact for minutes requests. In a nutshell, UT are just being procedural jerks here ... they could easily remedy the situation; but they prefer to bicker. I'll leave it to them to explain why.

In sum: UTSA is right, I forgot send a check, although one wonders why UTSA didn't make a tiny effort to remind me that they hadn't gotten their three bucks that would have avoided this. Just like the small effort I made to send Ms. Olson a copy of the IBC minutes request, despite her not being the NIH-indicated contact.

As to the question of who to contact for minutes at UT institutions, again, the public cannot be expected to have better information than OBA. In my view, NIH and UT need to work it out such that when I ask NIH for the appropriate contact, the contact that you provide is also the one that UT thinks is appropriate. Right now, you two don't agree.

Ms. Johnson, I'll send you the three bucks... don't let UTSA spend it all

in one place.

Sincerely,

Edward Hammond

At 8:30 AM -0500 3/19/07, Public Information Requests wrote:
Dr. Hammond.

Please see the attached letter and let us know if you cannot open the files.

Thank you.

Julie

*Julie Olson
The University of Texas at San Antonio
Office of the Vice President for Business Affairs
Main Building 3.102
One UTSA Circle
San Antonio, Texas 78249
Phone: (210) 475-1201
Fax: (210) 475-1118
Business Affairs. Your partner for successful solutions.*

Content-Type: application/octet-stream;
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Content-Description: NIH Letter 3-16-07.pdf

Content-Disposition: attachment;
filename="NIH Letter 3-16-07.pdf"

Attachment converted: Red Fish:NIH Letter 3-16-07.pdf (PDF /«IC»)
(00C0B67C)

X-MimeOLE: Produced By Microsoft Exchange V6.5

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Subject: FW: IBC Minutes Request Pursuant to the NIH Guidelines

Disposition-Notification-To: "Julie M Olson" <Julie.Olson@utsa.edu>

Date: Tue, 21 Mar 2006 13:26:33 -0500

Message-ID: <B8F071BA0CBA7347881043009E323525019033EA@granitel604>

X-MS-Has-Attach:

X-MS-TNEF-Correlator:

Thread-Topic: IBC Minutes Request Pursuant to the NIH Guidelines

Thread-Index: AcZNFGzEEVgB6k5tQEeqoMGnfVn6BDwAABvda

X-Priority: 1

Priority: Urgent

Importance: high

From: "Julie M Olson" <Julie.Olson@utsa.edu>

To: "Bennie Keckler" <Bennie.Keckler@utsa.edu>

Cc: "Jan Kruse" <Jan.Kruse@utsa.edu>,

"David R. Johnson \Provost Office\" <David.Johnson@utsa.edu>

Please provide the requested documents to this office by Tuesday March 28 2006. If there is information that you want to withhold, please let me know as soon as possible.

PLEASE NOTE:

You are required by law to submit all documents responsive to this request to the Office of the Vice President for Business Affairs. This office, with the assistance of the Office of General Counsel, reviews all documents and determines if any Texas Public Information Act exceptions apply.

Thank you

Julie Olson

Office of the Vice President for Business Affairs

Main Building 3.102

Phone: (210) 458-4201

Fax: (210) 458-4187

-----Original Message-----

From: Edward Hammond [<mailto:hammond@sunshine-project.org>]

Sent: Tuesday, March 21, 2006 12:22 PM

To: Public Information Requests

Subject: IBC Minutes Request Pursuant to the NIH Guidelines

The Sunshine Project

PO Box 41987

Austin TX 78704

15 March 2006

Director of Biosafety

University of Texas at San Antonio

6900 North Loop 1604 West

San Antonio TX 78249-0603

By fax: (210) 458-5658

Dear Director of Biosafety

Pursuant to the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section IV-B-2-a-(7), the Sunshine Project hereby requests the Minutes of all meetings of the University of Texas at San Antonio Institutional Biosafety Committee (IBC) since 1 May 2003.

Please send the minutes to the address above. The NIH Guidelines require that minutes be made available "upon request". I request that you send your reply by Friday, 28 April 2006.

This letter is sent to you because IBC registration records of the National Institutes of Health Office of Biotechnology Activities indicate that you are responsible for the University of Texas at San Antonio IBC.

This letter is sent to you as part of a national survey of compliance with the NIH Guidelines.

When you respond, I would appreciate your answer to the following question (please circle one).

The University of Texas at San Antonio IBC ☐ HAS / ☐ HAS NOT implemented written policies for the identification, review, and oversight of research involving any of the seven categories of experiments of concern identified by the National Academies of Science in its report *Biotechnology Research in an Age of Terrorism* (the "Fink Committee" report).

Johnson, Michelle (NIH/OD) [C], 3/19/07 10:23 AM -0700, Re: Response to NIH Compl

Please feel free to attach any additional explanatory materials that you feel are appropriate. Thank you very much for your attention to this request.

Sincerely,

Edward H. Hammond
Director

Content-Type: application/msword;
name="Hammond (Sunshine proj) 4-4-06.doc"
Content-Description: Hammond (Sunshine proj) 4-4-06.doc
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filename="Hammond (Sunshine proj) 4-4-06.doc"

Attachment converted: Red Fish:Hammond (Sunshine pr#C0B68B.doc
(WDBN/"IC") (00C0B68B)



The University of Texas at San Antonio

Vice President for Business Affairs

March 16, 2007

Michelle Johnson-Lancaster
IBC Coordinator
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Ste. 750, MSC 7985
Bethesda, MD 20892-7985

**Re: Complaint filed by the Sunshine Project (Edward Hammond) Relating to Documents
Requested from the University of Texas at San Antonio**

Dear Ms. Johnson-Lancaster:

On February 26, 2007, the University of Texas at San Antonio ("University" or UTSA) received notice of a complaint to your office. Pursuant to your request, the University writes to address this complaint.

Allegations:

Based on your letter we understand that Edward Hammond of the Sunshine Project alleges the University failed to comply with a request for copies of the University's Institutional Biosafety Committee ("IBC") meeting minutes.

University Response:

Specific to the request at issue, to the extent that Mr. Hammond's complaint stems from an inquiry he emailed to UTSA on March 21, 2006,¹ the requested IBC minutes were not provided to him, because he never responded to a University-issued invoice requesting payment for this information.

In this instance, the request was sent to the University's designated Public Information Officer and timely handled by UTSA (TAB 1). On April 4, 2006 the University issued an invoice for monies due in response to Mr. Hammond's inquiry (TAB 2). Mr. Hammond never paid this bill and, consequently, did not receive the information he requested.

¹ We note that the NIH did not send a copy of the specific request at issue with this notice of complaint. According to our records the March 21 request is the only request to UTSA left outstanding as noted above. If this assumption is incorrect, we will need a copy of the request we are alleged to have mishandled before we can respond to those case facts.

March 16, 2007

Page 2 of 3

Background and Rationale for Response:

Mr. Hammond has argued numerous times in the past that his requests are submitted pursuant to the guidelines imposed by NIH; he has made this same argument in the request at issue.

The University has repeatedly advised Mr. Hammond that although NIH guidelines speak to the public nature of IBC minutes, they do not provide a specific framework to which agencies can adhere in responding to such requests for information. Accordingly, under Texas law, the Texas Public Information Act ("TPIA") is the mechanism by which the public has access to government documents, including IBC minutes. There is no separate process utilized for documents subject to NIH guidelines.

In addition to providing a response framework, TPIA also provides cost rules that govern how and when a governmental body can assess and expect payment of charges. The University's invoice is in compliance with these rules. Had Mr. Hammond responded to the invoice and submitted payment, he would have received the IBC minutes he requested.

Your office has opined on the necessity of a standardized process for handling requests for IBC minutes. In a November 3, 2003 letter to a sister University of Texas campus, Dr. Amy Patterson wrote:

Redaction of IBC minutes – OBA's October 2 letter to Dr. Perachio spoke to the acceptability of redacting confidential or private information from IBC meeting minutes before release to the public. In its letter, OBA did not mean to exclude the redaction of information that might pose national or institutional security risks if released. However, OBA believes that such redaction should be done judiciously and would ask that UTMB develop and document criteria for how determinations of the need to redact on the basis of security considerations will be accomplished. Our concern is that this standard be applied consistently and only when truly necessary. (Emphasis added)

The uniform criterion requested by OBA in the above referenced letter already exists in the TPIA. Further, the Texas Attorney General is charged by statute to apply exceptions consistently and when necessary. Thus, because the University utilizes TPIA to address requests for public information, our use of the cost provisions outlined in TPIA is also appropriate and lawful according to both Texas law and the OBA.

Based on these facts, the basis of this complaint, that the University failed to respond to a request for information, is patently false. The University cannot violate NIH guidelines when, as in this instance, we have complied with the established process and the requestor neglects to pay applicable charges as allowed under state law.

We would note that TPIA includes a provision whereby the University is not required to address a re-request for information that has been previously made available to the requestor. Further,

March 16, 2007

Page 3 of 3

TPIA also allows 10-business days for a requestor to respond to an issued invoice; otherwise, the request is considered withdrawn by operation of law.

Although both provisions apply in the current situation, UTSA is willing to revisit this inquiry if Mr. Hammond is still interested in this information. As the University's Public Information Officer, Mr. Hammond may contact me about this request and pay his bill. My contact information is below:

By Mail:

Mr. Kerry Kennedy
Vice President for Business Affairs
University of Texas at San Antonio
One UTSA Circle
San Antonio, Texas 78249-0605

By Electronic Mail: publicinfo@utsa.edu

By Fax: (210) 458-4187

Full contact information for all the University of Texas System campuses can be found online at the following link: http://www.utssystem.edu/oge/openrecords/where_to_send_your_request.htm

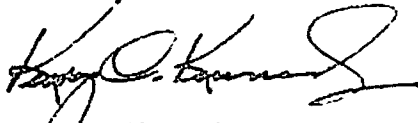
Conclusion:

The University did not fail to respond to the Sunshine Project's request for information. Rather, the requestor failed to respond to the University's invoice. The University fully complied with its portion of addressing this inquiry. Mr. Hammond neglected to make the requested payment to receive the documents he sought. He has no basis for complaint.

It is always our intention to handle all open record requests appropriately and in accordance with the law; therefore, it is our sincere hope that after review by your office we can consider this matter closed.

If you need additional information, please do not hesitate to contact me at (210) 458-4210

Sincerely,



Kerry L. Kennedy
Vice President for Business Affairs

Enclosures

cc:

Edward Hammond
hammond@sunshine-project.org

Julie M Olson

From: Julie M Olson
Sent: Tuesday, March 21, 2006 1:27 PM
To: Bennie Keckler
Cc: Jan Kruse, David R. Johnson (Provost Office)
Subject: FW: IBC Minutes Request Pursuant to the NIH Guidelines
Importance: High

Please provide the requested documents to this office by Tuesday, March 28, 2006. If there is information that you want to submit, please let me know as soon as possible.

PLEASE NOTE:

You are required by law to submit all documents responsive to this request to the Office of the Vice President for Business Affairs. This office, with the assistance of the Office of General Counsel, reviews all documents and determines if any Texas Public Information Act exceptions apply.

Thank you

Julie M Olson
Office of the Vice President for Business Affairs
425B Bldg. 3400
Phone: (210) 458-4201
Fax: (210) 458-4257

-----Original Message-----

From: Edward Hammond (<mailto:hammond@sunshine-project.org>)
Sent: Tuesday, March 21, 2006 12:22 PM
To: Public Information Requests
Subject: IBC Minutes Request Pursuant to the NIH Guidelines

The Sunshine Project
PO Box 41987
Austin, TX 78704

15 March 2006

Director of Biosafety
University of Texas at San Antonio
6900 North Loop 1604 West
San Antonio, TX 78249-0603

By fax: (210) 458-5658

Dear Director of Biosafety

Pursuant to the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section IV-B-2-a-(7), the Sunshine Project hereby requests the Minutes of all meetings of the University of Texas at San Antonio Institutional Biosafety Committee (IBC) since 1 May 2003.

Please send the minutes to the address above. The NIH Guidelines require that minutes be made available "upon request". I request that you send your reply by Friday, 28 April 2006.

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3/15/2007

When you respond, I would appreciate your answer to the following question (please circle one):

The University of Texas at San Antonio IBC HAS NOT implemented written policies for the identification, review, and oversight of research involving any of the seven categories of experiments of concern identified by the National Academies of Science in its report *Biotechnology Research in an Age of Terrorism* (the "Fink Committee" report).

Please feel free to attach any additional explanatory materials that you feel are appropriate. Thank you very much for your attention to this request.

Sincerely,

Edward H. Hammond
Director



The University of Texas ✶ San Antonio

Office of the Vice President for Business Affairs

Sent Via E-mail

April 4, 2006

The Sunshine Project
Attn: Edward Hammond
P.O. Box 41987
Austin, Texas 78704

Dear Mr. Hammond,

This letter is in response to your public information request to The University of Texas at San Antonio, received in our office on March 21, 2006. You requested *the minutes of all meetings of the University of Texas at San Antonio Institutional Biosafety Committee (IBC) since 1 May 2003*.

Under the current Texas Building and Procurement Commission guidelines, the estimated cost for copying these documents is \$.10 per page (\$3.30).

Pursuant to §552.2615, *Texas Government Code*, the requestor is required to take certain steps in order to avoid the withdrawal of the above-described request for information. This section of the Public Information Act requires:

- (1) the requestor to provide the governmental body with a mailing, facsimile transmission, or electronic mail address to receive the itemized statement (it is the requestor's choice which type of address to provide);
- (2) the governmental body to inform the requestor that the request is considered automatically withdrawn if the requestor does not respond in writing to the itemized statement within 20 business days after the date the statement is sent to the requestor. This response is limited by law to a response that the requestor will accept the estimated charges, will modify the request in response to the itemized statement, or has sent the Cost Rules Administrator at the Office of the Attorney General a complaint alleging that the requestor has been overcharged for being provided with a copy of the public information; and
- (3) the requestor to respond to the statement by delivering the written response to the governmental body either by mail, in person, by facsimile transmission, or by electronic mail.

In consideration of the above, if you agree to accept these charges, please so do in writing as detailed above. You may send a copy of this letter with a check or money order payable to "UTSA". Please address the envelope to the Office of the Vice President for Business Affairs, 6900 North Loop 1604 West, San Antonio, Texas 78249. The documents will be provided as soon as reasonable possible upon receipt of your payment.

This letter details the procedures for charges of copies of the material. If you wish to inspect the material at our office, which may be less costly, you may contact my office staff at (210) 458-4701 or via email at publicinfo@utsa.edu for further details.

Sincerely,

Kerry L. Kennedy
Vice President for Business Affairs

KLK:jmo
attachment



The University of Texas ★ San Antonio
Office of the Vice President for Business Affairs

Sent Via E-mail

April 4, 2006

The Sunshine Project
Attn: Edward Hammond
P.O. Box 41987
Austin, Texas 78704

Dear Mr. Hammond,

This letter is in response to your public information request to The University of Texas at San Antonio, received in our office on March 21, 2006. You requested *the minutes of all meetings of the University of Texas at San Antonio Institutional Biosafety Committee (IBC) since 1 May 2003*.

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- (3) the requestor to respond to the statement by delivering the written response to the governmental body either by mail, in person, by facsimile transmission, or by electronic mail.

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This letter details the procedures for charges of copies of the material. If you wish to inspect the material at our office, which may be less costly, you may contact my office staff at (210) 458-4201 or via email at publicinfo@utsa.edu for further details.

Sincerely,

A handwritten signature in black ink, appearing to read "Kerry L. Kennedy", with a stylized flourish at the end.

Kerry L. Kennedy
Vice President for Business Affairs

KLK/jmo
attachment

The University of Texas at San Antonio

CHARGE FOR COPIES OF PUBLIC RECORDS (Estimate)

Date: 04/04/06

Name of Requestor	<u>Edward Hammond</u>	Method of Payment:
Agency/Company	<u>Sunshine Project</u>	Cash: _____
Address:	_____	Check: _____
	_____	Money Order: _____
Telephone #	_____	
Description of Information	<u>IBC Minutes from meetings</u>	

	<u>Number</u>	<u>Total</u>
Standard-Size Paper Copies	33 @ \$0.10/page	3.30
	@ \$0.10/page	0.00
Nonstandard-Size Copies		
- Diskette	@ \$1.00/each	0.00
- Magnetic Tape (4 mm, 8 mm, 9-track)	@ \$11.00-\$13.50	0.00
- Data Cartridge	@ \$17.50-\$35.00	0.00
- Tape Cartridge (250 MB, 525 MB)	@ \$38.00 & \$45.00	0.00
- VHS Video Cassette	@ \$2.50	0.00
- Audio Cassette	@ \$1.00	0.00
- Oversized Paper (i.e., 11" X 17", greenbar, or bluebar)	@ \$0.50/page	0.00
- Mylar (36", 42", and 48")	@ \$0.85-\$1.35/linear ft.	0.00
- Blueprint/Blueprint Paper (all widths)	@ \$0.20/linear sheet	0.00
- Other (Official Transcript)	@ actual cost	0.00
Personnel Charges (includes fringe benefits)		
- Other Personnel Charges	@ \$15.00/hour	0.00
- Programming Time	@ \$26.00/hour	0.00
Overhead Charge		
- (20% of Total Personnel Charge)	0.00 x 20%	0.00
Microfiche/Microfilm Charges		
- Paper Copy	@ \$0.10/page	0.00
- Fiche/Film Copy	@ actual cost	0.00
Remote Document Retrieval Charge	@ actual cost	0.00
Computer Resource Charges		
- Mainframe	@ \$10.00/minute	0.00
- Midsized	@ \$1.50/minute	0.00
- Client/Server	@ \$2.20/hour	0.00
- PC or LAN	0.00 @ \$1.00/hour	0.00
Miscellaneous Supplies	0 @ actual cost	0.00
Postage/Shipping Charge	0.00 @ actual cost	0.00
Photographs	@ actual cost	0.00
Outsourced/Contracted Services	@ actual cost	0.00
Cost to Inspect (copy/replace)	0 @ \$0.10/page	0.00
		<u>\$0.00</u>
Total Charges*		\$ 3.30

Please make the check payable to

The University of Texas at San Antonio
Office of the Vice President for Business Affairs
6900 North Loop 1604 West
San Antonio, Texas 78249
(210) 458-4201

UTSA IBC Minutes Dates:

November 11, 2003
February 4, 2004
March 3, 2004
April 7, 2004
June 2, 2004
September 1, 2004
March 9, 2005
April 6, 2005
May 4, 2005
July 12, 2005
August 23, 2005
November 1, 2005
January 3, 2006
February 7, 2006

MEMORANDUM

To: University Standing Committee on Institutional Biosafety
Garry Sunter, Bernard Arulanandam, Esther Wheeler
Hans Heidner, Wendy McCoy, Richard Garza

From: Martha Lundell, Chair

Subject: Minutes from meeting on November 11, 2003

Present: Garry Sunter, Bernard Arulanandam, Esther Wheeler
Hans Heidner, Wendy McCoy, Richard Garza and Martha Lundell

Absent: Jonathan Allen and Mitch MaGee

Meeting was called to order at 2:00pm

First order of business was a discussion of the charge of the committee. The charge of the IBC at UTSA is "...to assure compliance with all federal regulations for the construction, handling and disposal of recombinant molecules, organisms and viruses containing recombinant DNA molecules and other biologically hazardous organisms and chemicals."

There was a discussion of whether IBC should be responsible for chemicals. The committee felt that chemical safety is not part of the NIH guidelines for the IBC and that the committee does not have the expertise or time to be responsible for chemical safety. A suggestion was made that the University should form a new Institutional Chemical Safety Committee to monitor chemical safety. The committee could consist of people from the Chemistry Department and possibly one member from the Biology Department. It was suggested that the word chemicals be removed from the IBC charge and replaced by the word toxins.

Several members asked where the approved protocols, files and documentation for the committee are located. Dr. Lundell said that she currently has all the material, and that it moves around with each new chair assignment. Dr. Sunter suggested that there should be a centrally located secure file for storing all IBC information.

There was discussion on the membership of the IBC. NIH guidelines are a minimum of 5 members, two of which are from outside the institution. In addition there are special member requirements depending on the type of work proposed. Two outside members Jonathon Allan and Mitchell Magee have agreed to serve on UTSA IBC. Wendy McCoy has agreed to be the Biological Safety Officer. There was a discussion on how to inform the Provost Office of who should be appointed to the IBC. A suggestion was made that a memo be sent to the Provost at the end of each year. It was mentioned that once Brooks is operating there should be a representative from that facility on the committee. It was also suggested that a roster for the committee be developed with individuals categorized by the expertise they could contribute to the committee.

There was discussion on how often the committee should meet. It was agreed that the committee will meet monthly, but if there is no new business the meeting can be cancel until the following month.

The discussion then turned to how to monitor biosafety issues at UTSA. Suggestions were made how to modify the routing form from Grants and Contracts and that there should be a statement of responsibility added to the form. It was also mentioned that there needs to be stricter surveying of ongoing projects and finding ways to make PI's understand their responsibility. A suggestion was made for an annual PI survey that would ask if protocol has changed, if there was no change the PI would just give the protocol number.

It was decided that Dr. Sunter, Dr. Heidner and Dr. Arulanandam would work on generating new application forms for Recombinant DNA, Transgenic Animals or Plants and Infectious Agents. The new forms will be submitted to the committee for approval. The goal of the Safety Office is to establish a website where forms for all research protocol approvals would be available, Rich Costello has agreed to initiate this project.

It was noted that the committee has never been registered with NIH and that this should be done soon.

A list was prepared for Dr. Lundell to discuss with David Johnson which included these topics:

1. Establishment of a Chemical Safety Committee
2. Appointment for committee members from a provided roster.
3. Official appointment letter for Wendy McCoy as Biological Safety Officer
4. Official appointment letters for outside members.
5. Administration help for running the IBC, perhaps in conjunction with IACUC and/or buyout for the chair position.
6. Registering IBC

It was suggested that the committee may need one more organizational meeting before inviting the outside members in to review research protocols.

Meeting adjourned at 3:35 pm.

Prepared by T.H. and M.J.L.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday February 4, 2004 Bioscience Building 3.03.10

Members Present:

Dr. Martha Lundell, Chair, Voting
Dr. Jonathan Allan, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Mitchell Magee, Voting
Ms. Wendy McCoy, Non-Voting
Dr. Garry Sunter, Voting
Dr. Esther Wheeler, Voting

Members Not Present:

Minutes Recorded By: Ms. Donna Loffman, Biosafety Coordinator

Meeting called to order at 8:35am

I. Approval of IACUC Minutes dated November 14, 2003

Approved

II. Discussion on Committee Membership:

- (1) Rich Costello will be added as Ex Officio without vote.
- (2) Wendy McCoy will also be Ex Officio without vote.
- (3) A representative member from Brooks will be added later (Jim Chambers was suggested).
- (4) Dr. Allan brought up the point that perhaps he and Dr. McGee don't really qualify as community members as stated in the NIH Guidelines. Both Wendy and Donna are each following up on a person who may be willing to serve as a community member. Both Jonathon and Mitch were invaluable to our discussion, we will keep both of them on board as we go through this development stage.
- (5) It was decided that rotating members (UTSA faculty) will serve 3 year staggered terms beginning in August and that the committee will elect the chairman.

III. Discussion on Registration Process:

- (1) Some suggestions were made for the cover letter, Martha will draft a new copy. It was suggested that the registration should be sent as soon as possible.
- (2) Martha will concurrently develop our letter to the university faculty outlining the function of the committee and faculty compliance.
- (3) Martha and Rich Costello will work on Website
- (4) Martha needs to remind David Johnson to draft a letter for Wendy's BSO appointment.

IV. Process of reviewing applications and Meeting times:

- (1) Committee will meet on first Wednesday of each month at 8:30 a.m. in BSB 3.03.10
- (2) Applications must be submitted to the committee two weeks before the meeting.

V. Discussion of Application forms:

- (1) It was suggested that on the infectious agent application a question be added to ask for a few more details on the animal, plant or tissue use protocol.
- (3) A Protocol numbering system was discussed = **I-001-02/05 A0**
 - (a) 1-letter code indicating **I**nfectious, **R**ecombinant or **T**issue
 - (b) Unique 3-digit number identifying the particular protocol
 - (c) 4-digit number indicating the month / year the protocol will expire
 - (d) A number indicating whether or not any amendments have been approved for the particular protocol
i.e. A0= no amendment, A1= one amendment, A2= two amendments etc.
- (4) Protocols will be valid for 3 years, investigators will be sent a Renewal Request by Coordinator

v.I.

Discussion of Applications:

(1) Hans Heidner's last three applications

The applications had already been approved by email and there were no additional concerns.

(2) Bernard Arulanandam's application for use of Tularemia

A number of questions were discussed. Dr. Lundell will prepare a memo listing the concerns and Dr. Arulanandam will provide a written response. (See attachment).

VII. Discussion of Committee Liability

Several Committee members wondered about their liability serving on the IBC. Martha will look into this further.

Meeting adjourned at 10:30 a.m. The next meeting is scheduled for Wednesday, March 3rd 2004 at 8:30 a.m. in the Bioscience Building Conference Room, BSB 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday March 3, 2004 Bioscience Building 3.03.10

Members Present:

Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Mitchell Magee, Voting
Ms. Wendy McCoy, Non-Voting
Dr. Garry Sunter, Voting

Members Not Present: Dr. Jonathan Allan, Voting
Dr. Esther Wheeler, Voting
Mr. Rich Costello, Non-Voting

Minutes Recorded By: Ms. Donna Loffman, Biosafety Coordinator

Meeting called to order at 8:35am

- I. Approval of Institutional Biosafety Committee Minutes dated 2-4-04.**
Approved
- II. Discussion of separate committee for select agents – As Follows:**
(1) It was determined there would be two committees with the same members. IBC would meet first with public record minutes and Select Agents would meet second with closed minutes. The Select Agents committee would require reappointment by the provost.
- III. Discussion of outside committee member – As Follows:**
(1) Alvin Stewart was brought up and Martha will check with the Metropolitan Health District for a lead.
(2) Martha will send registration to NIH with existing committee members.
(3) New outside committee member will join in September.
- IV. Final approval of Registration and Faculty Letters – As Follows:**
(1) Approved with modification to read Infectious / Microbial
(2) Both NIH Registration and letter to the Faculty will be sent from the Provost's office.
- V. Review of Website – As Follows:**
(1) Check NIH Guidelines to research additional url's to link.
(2) Modify forms to be consistent
- VI. Liability of committee members – As Follows:**
(1) Committee is protected, Martha will resend email for official legal protection.
- VII. Approval / Disapproval of New Applications – As Follows:**
Dr. Bernard Arulanandam - "Innate and Adaptive Immunity to *F. tularensis*"
(1) Approved pending CDC Registration Letter
Dr. Richard LeBaron "Tumor Suppression Activity of Beta-ig"
Tabled Pending Modifications - email notification to Dr. Richard LeBaron
(1) Page 1 – Yes Tissue will contain a known Infectious agent
(2) Page 1 – What type of human tissue?
(3) If Human tissue will universal precautions be taken?
(4) Have personnel been trained in Blood Born Pathogens?
(5) Will any work be done outside the lab, i.e. histology suite
- VIII. Use of infectious agents in common equipment rooms or storage areas.**
(1) Rooms and freezers should be labeled – Wendy will look into mechanism
(2) Sign should be left on any piece of equipment while in use if contains infectious material.
(3) As long as above precautions are taken, using BSL-2 agents in common area is approved.

Meeting adjourned at 10:30 a.m. The next meeting is scheduled for Wednesday, April 7th 2004 at 8:30 a.m. in the Bioscience Building Conference Room, BSB 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday April 7, 2004 Bioscience Building 3.03.10

7

Members Present:

Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Mitchell Magee, Voting
Ms. Wendy McCoy, Non-Voting
Dr. Garry Sunter, Voting
Dr. Jonathan Allan, Voting

Members Not Present:

Dr. Esther Wheeler, Voting
Mr. Rich Costello, Non-Voting

Minutes Recorded By: Ms. Donna Loffman, Biosafety Coordinator

Meeting called to order at 8:30am

I. Approval of Institutional Biosafety Committee Minutes dated 3-3-04.

Approved

II. Discussion of separate committee for select agents – As Follows:

- (1) It was determined there was no need for separate committees with the same members. NIH requires IBC and Select Agent minutes to be public record.
- (2) Refer any request for minutes to Jim Phillips @ Systems (Legal).
- (3) Rich will bring up point to EAC meeting in May

III. Discussion of meeting with David Johnson – As Follows:

- (1) Registration – Approved
- (2) Faculty Memo – Distributed 3/15/04
- (3) Next year roster – to be determined at next meeting. (New Chair=?, Rotate Jim Chambers=On, Esther Wheeler=Off, Mitch Magee=Off, Phillip Vaughn=On)
- (4) Martha to check whether personnel should be updated regularly or only on our anniversary date.

IV. Changes in Applications – As Follows:

- (1) Add toxins to infectious agents application
- (2) Top of form and A and B to distinguish between teaching and research labs
- (3) Review of teaching lab activities – Add to top "Types – Teaching Lab etc."
- (4) Vertebrate tissue application – Change type of tissue to read "Vertebrate" and under training add requirement for the Bloodborne Pathogens Training.

V. Review of Website – As Follows:

- (1) Still needs Updating
- (2) Would like to see one site with all 5 Compliance Committees
- (3) Should there be limited access?

VI. Approval / Disapproval of New Applications – As Follows:

I9-03/07 Dr. Bernard Arulanandam

Score 1 - Approved - Received CDC Registration Letter

T1 - Dr. Richard LeBaron

Score 3 - Tabled Pending Modifications – Have not received response from Dr. Richard LeBaron on committee questions

- (1) Page 1 – Yes Tissue will contain a known Infectious agent
- (2) Page 1 – What type of human tissue?
- (3) If Human tissue will universal precautions be taken?
- (4) Have personnel been trained in Blood Born Pathogens?

(5) Will any work be done outside the lab, i.e. histology suite

I10 - Mr. Loyd Hays

Score 2 - Approved Pending Modifications – email notification to Dr. Loyd Hays

- (1) Questions on student protective equipment – gloves, eye ware and coats should be mandatory
- (2) Document change of personnel on regular basis
- (3) What special precautions are taken on experiments with unknowns
- (4) Do students do their own throat swabs or on each other?
- (5) How are bacteria assessed for attenuation?

Dr. Chris Coteff – “Anatomy Teaching Labs”

It was decided that since all specimens are preserved an application was not necessary.

A Note should be added to the application to clarify.

VII. Dr. Charles Wilson's Inquiry – Using small quantity under 100mg

- (1) How much at a time is weighed out?
- (2) Where is it stored? Is it locked?
- (3) Applications should be required.

VIII. Awareness and Enforcement – As Follows:

- (1) Who else should be submitting these forms? - Add toxins Yes / No to safety survey to identify.
- (2) Which recombinant experiments are exempt? – Will discuss next meeting.

IX. Accident Protocol – As Follows:

- (1) Operating Handbook – Rich and Wendy working on Biological Safety Manual for Chemical Lab for Committee review in 2 months.
- (2) Specific Manual for BSL-3.

X. Opening of BSL-3 – As Follows:

- (1) Finalizing preconstruction meetings

Meeting adjourned at 10:15 a.m. The next meeting is scheduled for Wednesday, May 5th 2004 at 8:30 a.m. in the Bioscience Building Conference Room, BSB 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday June 2, 2004 Bioscience Building 3.03.10

Members Present: Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Mitchell Magee, Voting
Ms. Wendy McCoy, Non-Voting
Dr. Garry Sunter, Voting
Phillip Vaughan, Voting
Dr. Jonathan Allan, Voting
Members Not Present: Dr. Esther Wheeler, Voting
Mr. Rich Costello, Non-Voting
Dr. Hans Heidner, Voting
Minutes Recorded By: Ms. Donna Loffman, Biosafety Coordinator

Meeting called to order at 8:32am

- I. Approval of Institutional Biosafety Committee Minutes dated 4-7-04.**
Approved
- II. Discussion of committee roster and chairman for next academic year– As Follows:**
(1) It was determined Chairman will send an email for nominations to be returned to Coordinator
- III. Discussion of issues related to "Freedom of Information Act" – As Follows:**
(1) Preparation of IBC Minutes do not need to state Principal Investigator's name or location
(2) Application will only be identified by protocol number
- IV. Changes in Applications – As Follows:**
(1) Added Microbial Agent, Infectious Agents and Toxins
(2) Need to revise application to get information on more than 100mg of toxins page 1 C*If yes, explain handling procedure
(3) Vertebrate tissue application – Change type of tissue to read "Vertebrate" and under training add requirement for the Bloodborne Pathogens Training.
- V. Review of Website – As Follows:**
(1) Updating
- VI. Approval / Disapproval of New Applications – As Follows:**
T1 - Dr. Richard LeBaron
Score 3 - Tabled Pending Modifications email notification to PI
Although a response was submitted to initial request for more information the committee still has concerns
(1) Fixation procedure
(2) How is agent transported/packaged?

T2 – Dr. Chris Coteff
Score 1 – Approved No expiration date

I10 - Dr. Loyd Hays
Score 1 - Approved–No expiration date email notification to PI

I11 – Dr. Karl Klose
Score 3 – Tabled Pending Committee Review – email notification to PI
(1) Needs to supply supplementary information with application
(2) Need more information on shipping procedure
(3) More specific on how agent will be genetically modified

- (4) More specific on animal protocol
- (5) Personnel have not been through UTSA Biosafety or Bloodborne Pathogen Training

I12 – Dr. Karl Klose

Score 3 – Tabled Pending Committee Review – email notification to PI

- (1) Cholera Toxin and Bio-warfare applications should be separated, there should be an application per funding source
- (2) Again more specificity is needed on application

I13 – Dr. Stephanie Elliot

Score 2 – Tentative Approval Pending Modifications - email notification to PI

- (1) Is raw sewage really at the RSG1 level? How was this determined?
- (2) What type of protection or safety precautions are being used?
- (3) Who collects the samples from Cibolo Creek?
- (4) What is the transportation procedure?

Meeting adjourned at 10:45 a.m. The next meeting is scheduled for Wednesday, July 7th 2004 at 8:30 a.m. in the Bioscience Building Conference Room, BSB 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday September 1, 2004 Bioscience Building 3.03.10

Members Present: Dr. Martha Lundell, Chair, Voting
Dr. Jonathan Allan, Voting
Dr. Bernard Arulanandam, Voting
Dr. James Chambers, Voting
Dr. Hans Heidner, Voting
Ms. Wendy McCoy, Non-Voting
Mr. Brian Moroney, Non-Voting
Dr. Garry Sunter, Voting
Mr. Phillip Vaughan, Voting

Members Not Present: n/a

Minutes Recorded By: Ms. Donna Loffman, Biosafety Coordinator

Meeting called to order at 8:30am

I. Approval of Institutional Biosafety Committee Minutes dated 06-02-04.

Approved

II. Discussion of committee roster and chairman for next academic year-- As Follows:

- (1) It was determined Chairman will remain, rotating off will be E Wheeler, M Magee is moving and R Costello is no longer with UTSA. Rotating on will be: Dr. James Chambers, Mr. Phillip Vaughan and Mr. Brian Moroney. Dr. Lundell will send memo to NIH with Roster changes

III. Applications -- As Follows:

I11

Score 2 -- Tentative Approval Pending Modifications -- email notification to PI

- (1) List the exact tularensis species you will be using (A & B forms)
- (2) Provide a statement on why the genetic modifications you intend to make are unlikely to increase virulence
- (3) Provide a statement on the antibiotic resistance of your agent and how your experiments are unlikely to change this resistance
- (4) Provide a statement on how genetic material leaving the BSL3 will be tested to insure it is not infectious
- (5) Provide information on what mechanisms are in place for vector control within the BSL3 facility
- (6) List who will be providing serological testing of personnel
- (7) Address whether a tularensis vaccine under review by the FDA is available for use by laboratory personnel and if so the practicality of vaccinating UTSA personnel

I12

Score 2 -- Tentative Approval Pending Modifications -- email notification to PI

- (1) Provide information on where you might ship this agent and what guidelines would be followed
- (2) Provide a statement on why the genetic modification you intend to make are unlikely to increase virulence

I13

Score 1 -- Approved - email notification to PI

- (1) Suggest the use of plastic aprons for personnel handling raw sewage.

IV. Discussion of Mr. Hays inquiry on students who are immunocompromised -- As Follows:

- (1) Wendy McCoy suggested making changes in the Lab Safety Manual and that hopefully immunocompromised employees would be identified during the mandatory lab safety training. Dr. Hays has been talking to legal council about having waivers for students in the classroom laboratories.

V. Discussion on how to handle special requests for reviewing applications after the filing deadline – As Follows:

- (1) Deadline is 15th of month prior to meeting on first Wednesday of each month
- (2) Will send Renewal requests to PI's 60 days prior to expiration
- (3) Expedite Review Request must be made in writing to the chair and will be handled on a case by case basis.

VI. Old Business – To be covered at next meeting

- (1) T1 application
- (2) Website
- (3) Discussion of autoclaves
- (4) Awareness and Enforcement
 - (a) Hazard Assessment – Wendy's survey
 - (b) Routing Form
 - (c) Small quantities of toxins
- (5) Biosafety Manual

Meeting adjourned at 10:30 a.m. The next meeting is scheduled for Wednesday, October 6th 2004 at 8:30 a.m. in the Bioscience Building Conference Room, BSB 3.03.10 DAR.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday, March 9, 2005 Bioscience Building 3.03.02

Members Present: Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Garry Sunter, Voting
Mr. Phillip Vaughan, Voting
Ms. Wendy McCoy, Non-Voting

Members Not Present: Dr. Jonathan Allan, Voting
Dr. James Chambers, Voting
Dr. Brian Moroney, Non-Voting

Minutes Recorded By: Ms. Suzette Vallejo, Interim Biosafety Coordinator

Meeting called to order at 8:30 a.m.

I. Approval of Institutional Biosafety Committee Minutes dated 06-02-04.
Approved

II. Recommendation on BSL-3

- (1) Committee members took a tour of the facility and commented that the facility is well designed.
- (2) Dr. Arulanandam mentioned the fear factor of UTSA Facilities Services employees and asked how this could be remedied. The Facilities Services employees are the ones who will make repairs to the BSL-3 lab. Dr. Arulanandam recommends that Ms. McCoy meet with the appropriate UTSA Facilities Services officials to determine what supervisory controls are in place and make recommendations concerning the BSL-3 lab safety issues. Dr. Sunter mentioned that companies usually have specially trained people for BSL-3 facilities should any of the technical equipment need repair.
- (3) Dr. Lundell commented that there is a difference between taking the BSL-3 safety-training course and the practical application of those procedures. Dr. Arulanandam said that safety has to come first and experiments come second.
- (4) Dr. Sunter commented that the autoclave is adequate at this time and that he will remain the contact person for the autoclaves.
- (5) Ms. McCoy has posted the standard operating procedures outside the BSL-3.
- (6) The committee approved the BSL-3 laboratory for operation.

III. Discussion of committee roster for next academic year:

- (1) Dr. Lundell will step down as chair of the UTSA IBC on September 1st. Dr. Jonathan Allan and Dr. Jim Chambers will also need to be replaced.
- (2) The UTSA Institutional Biosafety committee needs to submit recommendations of the new IBC members by the beginning of this summer, so that the provost office can make the appointments for the fall.
- (3) The NIH renewal is due on October 4th.

- (4) Noe Saldana, Office of Research and Development has posted a new position titled "The Research Compliance Officer," who is supposed to oversee the four institutional safety committees.
- (5) Dr. Arulanandam suggested Drs. Klose, Teale or Cole for the chair and said he would ask them. Dr. Lundell suggested that the new chair should participate in meetings before September 1st.
- (6) It was suggested that Dr. Chaudry be asked to serve for the Brooks facility. And several suggestions were made for the outside member.

IV. Discussion of survey and exempt experiments:

- (1) Dr. Lundell presented a survey to be completed by all principle investigators. Faculty will be prohibited from submitting grant applications without a copy of UTSA IBC Survey on file. Faculty will be asked to periodically update the UTSA IBC Survey. The survey form would be posted on the IBC website.
- (2) The committee agreed the survey is a good idea, should be implemented quickly and should come from David Johnson's office.
- (3) Suggested changes in UTSA IBC Survey form - As Follows:
Page 1, item 1: Add a box for "Pending" application, since approval of a biosafety protocol is not necessary for grant submission.
Page 1, item 3: Revise title as follows: "Vertebrate Tissue – including human or other primate cell lines".
- (4) There was discussion on the types of experiments that should be exempt from IBC review. Dr. Lundell asked the committee to help review this document for discussion at the next meeting.

V. Applications- As Follows:

R1 Score 1- Approved - email notification to PI

- (1) Ms. McCoy stated that should the work progress to human cell lines that the personnel must take the Blood borne Pathogen Training course on a yearly basis.

VI. OLD BUSINESS: was not addressed

Website

Autoclaves

Biosafety Manual

Meeting adjourned at 10:10 a.m. The next meeting is scheduled for Wednesday, April 6, 2005 at 8:30 a.m. in the Bioscience Building 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday, April 6, 2005 Bioscience Building 3.03.10

Members Present: Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Garry Sunter, Voting
Mr. Phillip Vaughan, Voting
Ms. Wendy McCoy, Non-Voting

Members Not Present: Dr. Jonathan Allan, Voting
Dr. James Chambers, Voting
Mr. Brian Moroney, Non-Voting

Minutes Recorded By: Ms. Suzette Vallejo, Interim Biosafety Coordinator

Meeting called to order at 8:30 a.m.

I. Approval of Institutional Biosafety Committee Minutes date 03-09-05. Approved

II. New Business

Discussion on merging the three applications:

Dr. Heidner, Dr. Sunter and Dr. Lundell discussed the idea of merging the three applications into one. This will be easier for investigators whose projects span more than one area and it will be easier administratively. The IBC members approved the revised UTSA Biosafety application.

Final approval of IBC survey and list of exempt experiments-As Follows:

IBC Survey: It was suggested that this form be submitted with each grant application. Changes in wording should be made on the survey, the website and the letter from the Provost to reflect this change. For implementation of the IBC Survey it was decided that the letter from the Provost Office should be sent out to everyone campus wide.

List of Exempt Experiments:

- (a) It was suggested that all references to websites should be made into links.
- (b) Exempt Microbial agent, infectious Agents or Toxin Experiments:
 - 1) Dr. Sunter suggested that BL1-P be added to the exempt category, although he would look up the exact definition of this category.

- 2) Dr. Heidner suggested with respect to toxin amounts to simply supply the CDC link that lists the amounts that can be stored.
- 3) Dr. Heidner suggested that we look at the ATCC site to determine which vertebrate cell lines should be reviewed by IBC.

Discussion of revised website:

The website met with approval.

Length of time for renewals-

The committee agreed to leave the renewal time at 3-years.

Should renewals be reviewed by committee or just the chair?

The committee decided that renewals should be reviewed by all committee members.

III. Applications- As Follows:

I3

Score 1 – Approved – email notification to PI

- 1) Page 1, item F: Ms. Wendy McCoy mentioned the new guidelines regarding the shipping or transporting of agents from the university. Ms. McCoy will discuss with Brian Moroney about having training classes at UTSA in the near future.

I2 + R2

Score 1 – Approved – email notification to PI

- 1) Page 4, item 4: Confirm laboratory personnel training for Jun Tu and Suren Baliji.
- 2) With the new application procedure these two applications will be combined into one application.

I1

Score 1 – Approved – email notification to PI

- (1) Page 9, item 3: Change the room number to 1.03.32.

R3

Score 1 – Approved – email notification to PI

- 1) In general the committee suggested that this protocol get non-expiration status.
- 2) However the use of a human cell line may require a tissue application and bloodborne pathogen training. Dr. Lundell will investigate this further.

I14

Score 2 - Tentative Approval Pending Modifications- email notification to PI

1. Dr. Arulanandam should not be listed on the application.
2. A copy of Dr. Teale's CDC approval letter is required.

3. Where will she be shipping this agent and how?
4. There are contradictory statements on page 3, stating that IRB approval is not necessary but that an IRB application is pending.
5. If biological material will be removed from the BSL-3 how will decontamination be ensured and what will be the test for viability.
6. Where will any preparative work for the BSL-3 be done and where will any subsequent work on material removed from the BSL-3 be done?
7. The wrong room is listed for the BSL-3 under performance site.
8. More detail is needed on safety procedures. Reference should be made to the existing BSL-3 safety manual and training course. All personnel must have the UTSA specific laboratory safety training, blood borne pathogen training and BSL-3 training. All personnel must undergo serological testing, how will this be accomplished?
9. Revised application should be on the latest version of the UTSA IBC application.

V. **OLD BUSINESS**

Discussion of committee roster for next academic year: Juliani Chaudry will replace James Chambers for next academic year. Dr. Lundell is rotating off and the IBC will need to find a replacement. Also, the IBC will have to find a replacement for Jonathon Allan.

Biosafety Manual: None

Meeting adjourned at 10:45 a.m. The next meeting is scheduled for Wednesday, May 4, 2005 at 8:30 a.m. in the Bioscience Building 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Wednesday, May 4, 2005 Bioscience Building 3.03.10

Members Present: Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Garry Sunter, Voting
Mr. Brian Moroney, Non-Voting
Ms. Wendy McCoy, Non-Voting

Members Not Present: Dr. Jonathan Allan, Voting
Mr. Phillip Vaughan, Voting
Dr. James Chambers, Voting

Minutes Recorded By: Ms. Suzette Vallejo, Interim Biosafety Coordinator

Meeting called to order at 8:41 a.m.

I. Approval of Institutional Biosafety Committee Minutes date 04-06-05. Approved

II. New Business

Application:

One question has been added with regard to removing material from the BSL3. The change was approved. Dr. Arulanandam and Klose will work on writing a policy for the BSL3 operation manual on how to remove material from the BSL3.

New Numbering System: Dr. Lundell mentioned that there is a new numbering system. She has already converted the old applications to the new numbering system.

Final approval of IBC survey and list of exempt experiments-As Follows:

There are two UTSA IBC survey forms on the website:

- One general UTSA Survey form.
- One UTSA Survey form for grant submissions. It was suggested that this form be submitted with each grant application.

List of Exempt Experiments:

Dr. Lundell suggested adding the following information to the Exempt Vertebrate Tissue/Cell Line Experiments: "The ATCC lists the biosafety containment level for many vertebrate cell lines. Protocols that use cell lines which are BSL2 or higher require a Biosafety Application. Protocols that use BSL-1 cell lines are not automatically exempt from review; researchers should consult with the IBC for clarification."

If a person has experience with human cell lines approval for BSL-1 is not necessary, but if it is the first time an investigator is using human cell lines an application should be required.

Website-Update

- The new IBC Application is available on the website.
- The two survey forms are available.
- Dr. Sunter suggested that IT setup a BioSafety email for the IBC Chair.

The committee agreed to release the IBC Survey form.

III. Applications- As Follows:

B16

Approved– email notification to PI

- 1) Dr. Mueller's application from last time was considered as a no expiration status with the exception, that he had a human cell line listed on the application. The human cell line was an actual BSL-2 cell line. Dr. Lundell spoke with Dr. Mueller and he has decided to cross it off his application. Dr. Mueller was given a no exempt status. Dr. Mueller will submit a new application, once he decides to work with the human cell lines in the near future.

B17

Approval Pending – email notification to PI

- 1) What about the Biosafety cabinet?
- 2) When directly handling the tissue, a disposal face shield and gloves protection needs to be utilized.
- 3) If it's fixed, how long? Are you using 3.5% or 6.5%, how long? If it's not fixed, can you write a statement of the BLS-2 conditions which you will be using?

B18

Approval Pending– email notification to PI

- (1) Page 2, item 3: Laboratory Personnel: Jennifer Schultz must attend the LST and BPT training courses required by UTSA.
- (2) There is no statement on whether the tissue will be fixed or not, or what safety precautions will be taken for unfixed tissue.
- (3) More detail is needed on how the tissue will be transported.

B19

Approval Pending– email notification to PI

Provide when available:

- 1) CDC Select Agent Approval letter.
- 2) USDA Approval letter.
- 3) Relevant IACUC protocol numbers.
- 4) Update on the UTSA training your personnel complete.
- 5) A copy of CDC certification for West Campus BSL3.

- 6) A copy of the BSL3 Biosafety Manual for Coccidioides.
- 7) What type of mask or respirators will you be using?

B20

Approval Pending– email notification to PI

Provide when available

- 1) Relevant IACUC protocol numbers.
- 2) Update on the UTSA training your personnel complete.
- 3) Where you going to house these animals?

V. OLD BUSINESS

Dr. Sunter asked how the committee is going to deal with radioactive biohazards.

Discussion of committee roster for next academic year: Juliani Chaudry will replace James Chambers for next academic year. Dr. Lundell is rotating off and the IBC will need to find a replacement. Also, the IBC will have to find a replacement for Jonathan Allan.

Biosafety Manual: None

Meeting adjourned at 9:53 a.m. The next meeting is scheduled for Wednesday, June 1, 2005 at 8:30 a.m. in the Bioscience Building 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Tuesday, July 12, 2005 Bioscience Building 3.03.10

Members Present: Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Garry Sunter, Voting
Mr. Brian Moroney, Non-Voting
Ms. Wendy McCoy, Non-Voting
Mr. Phillip Vaughan, Voting

Members Not Present: Dr. Jonathan Allan, Voting
Dr. James Chambers, Voting

Minutes Recorded By: Ms. Suzette Vallejo, Interim Biosafety Coordinator

Meeting called to order at 9:07 a.m.

I. Approval of Institutional Biosafety Committee Minutes date 05-04-05. Approved

II. New Business

There was a discussion on Jim Lewis' concern about radioactive material leaving the BSL-3 facility. His main issue is that material be logged so if necessary the source can be determined. Dr. Arulanandam and Dr. Klose will be working together on a process to keep track of materials that leave the BSL-3 facility.

Dr. Arulanandam mentioned that swipe card locks on the BSB doors should be expedited and that people should be careful about unidentified persons that sneak in behind someone once the door is opened.

III. Applications- As Follows:

B17-B18

Approved - email notification to PI

Dr. LeBaron has addressed all the previous concerns of the committee.

B19

Approval – email notification to PI

Dr. Lundell notified Dr. Cole that respirators are required in the BSL-3, and that the IBC would prefer that they also be mandatory in the new West Campus BSL-3 when that facility opens

B5

Approved – email notification to PI

B21

Approval Pending - email notification to PI

1. On page 2, under part B you should mark the Type B as RG2 and BSL-2 and mark Type A as RG3 and BSL-3. Neither of these are RG4.
2. On page 2, part F, under shipping procedure you should state that you will review UTSA specific policies regarding shipping and if necessary take the UTSA shipping training course.
3. On page 3 where you indicate that "all tubes/containers will be swipe tested", it should be stated that "all tubes/containers will be decontaminated and then swipe tested prior to removal"
4. On page 5 you should indicate that KK214 is a tularemia strain.
5. On pages 4 and 9, Basic Science building should be changed to BioScience building.

New Application

Approval Pending- email notification to PI

1. Section C, provide IACUC protocol #.
2. Section C, under disposal; what % of bleach will be used and for how long? Bleach deteriorates and must be replaced regularly.
3. Section C, under shipping; describe the procedure that will be used to ship material. Have any personnel taken the shipping class from Wendy McCoy?
4. Section C, under safety procedures; specifically describe what precautions will be taken to protect personnel.
5. Section D, under location of stored material; where in BSB 2.03.44 will the material be stored?
6. Section F, the summary does not specifically describe the procedure, the safety issues and what safety precautions will be followed.

New Application

Approval Pending- email notification to PI

1. Section A, part F, describe shipping procedure in more detail. Have any personnel taken the shipping training class from Wendy McCoy?
2. Section D, where in the laboratory will the agent be stored?
3. Section D, describe how the agent will be disposed.
4. Section E, list the training of personnel.
5. Section F, the summary does not specifically describe the procedure, the safety issues and what safety precautions will be followed.
6. Should you eventually develop a pig model this will require a new biosafety application.

IV. Results from Surveys:

- Dr. Lundell has made a couple of changes to the survey.
- She sent two or three reminders to the Department of Biology, faculty members to get them to respond.
- The IBC suggested that the surveys should be given to Ms. McCoy who will review them as she does her laboratory inspections. If she feels the

investigator needs to submit an application form, she will notify that faculty member and the IBC.

- Dr. Lundell talked to Noe Saldana in Research Development about having a survey required with each grant application. The development office seems reluctant to get involved in this process, but Noe has said that the routing form is under revision and will more specifically address biosafety.

V. Discussion of committee roster for next academic year:

- Juliani Chaudry will replace James Chambers for next academic year.
- Dr. Lundell is rotating out and Dr. Karl Klose will join the committee as Dr. Lundell's replacement.
- Also, the IBC will have to find a replacement for Jonathan Allan.
- The NIH renewal is due by October 4th 2005.

VI. NIH Meeting:

- The NIH meeting is scheduled for Thursday, August 18 – Friday, August 19, 2005 in San Antonio, Texas. Ms. McCoy and Mr. Moroney are planning to attend.

VII. OLD BUSINESS:

Biosafety Manual: None

Meeting adjourned at 10:30 a.m. The next meeting is scheduled for Tuesday, August 23, 2005 at 9:00 a.m. in the Bioscience Building 3.03.10.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Tuesday, August 23, 2005 Bioscience Building 2.03.02D

Members Present: Dr. Martha Lundell, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Hans Heidner, Voting
Dr. Garry Sunter, Voting
Ms. Wendy McCoy, Non-Voting
Mr. Phillip Vaughan, Voting
Members Not Present: Dr. Jonathan Allan, Voting
Dr. James Chambers, Voting
Mr. Brian Moroney, Non-Voting
Minutes Recorded By: Dr. Martha Lundell

Meeting called to order at 9:07 a.m.

I. Approval of Institutional Biosafety Committee Minutes date 07-12-05. Approved

II. New Business

Wendy McCoy said that she and Brian Moroney would prefer to wait until the next meeting to discuss what they learned at the NIH/IBC Conference. She also said that NIH will be contacting various institutions to collect information on how IBC committees are run.

Wendy McCoy mentioned that she will be taking a course in how to ship biohazardous materials and then will establish a course for UTSA personnel.

Dr. Lundell stated that on the biosafety surveys several people had listed their IRB protocol numbers under the vertebrate tissue section to certify their protocol. She wanted to point out that this is not appropriate since the IRB application only deals with consent issues and not safety issues. Investigators using human tissue should file both an IRB protocol and a Biosafety application.

III. Applications- As Follows:

New Application 1

Approval Pending— email notification to PI

1. Section A-1B. Why are both risk group 1 and 2 marked for this organism? If it is a level 1 organism but you plan to use level 2 containment you should indicate this more clearly.
2. Section A-2B. Animals will be stored in the West Campus animal facility SAL 1.03.32.

3. Section A-2B. After autoclaving infected animals, how will the material be disposed? Please consult with Wendy McCoy or Rich Garza at the Office of Environmental Health Safety and Risk Management for proper UTSA procedure.
4. Section C-1. Is the tissue from SkinEthic human tissue?
5. Section C-1. Where will the serum samples come from and what precautions will be taken for shipping?
6. Section C-1. Autoclave tissue is not disposed of in regular waste. Please consult with Wendy McCoy or Rich Garza at the Office of Environmental Health Safety and Risk Management for proper UTSA procedure.
7. Section E. All personnel will need to receive UTSA specific training; Laboratory Safety Training and Bloodborne Pathogens Training. At least one individual will need to receive training for shipping biohazardous material.

New Application 2

Approval Pending- email notification to PI

1. Section A-1B. You have marked risk group 2, does this apply to both organisms? If so you should state this or make specific marks for each organism.
2. Section A -1F. How will you transport the material from UTHSCSA to UTSA?
3. Section A-2B. Animals will not be stored in the Tobin Building but the SAL 1.03.32.
4. Section A-2B. After autoclaving infected animals, how will the material be disposed? Please consult with Wendy McCoy or Rich Garza at the Office of Environmental Health Safety and Risk Management for proper UTSA procedure.
5. Section E. Jorge Alvarez will need to obtain UTSA Lab Safety Training and Bloodborne Pathogen Training.

IV. Discussion of committee roster for next academic year:

- Dr. Lundell said that the previous person suggested as an outside member had declined the offer.
- Dr. Lundell sent the suggested committee members forward to the Provost.
- The NIH renewal is due by October 4th 2005.
- There was discuss on the need of the University to find administrative support for the IBC.

V. OLD BUSINESS:

Biosafety Manual: Wendy McCoy stated that the manual is in progress and she hopes to have it ready for review some time during the Fall semester.

Meeting adjourned at 10:30 a.m.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Tuesday, November 1, 2005 Tobin Building, Conference Room # 1.102

Members Present: Dr. Jose Lopez-Ribot, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Karl Klose, Voting
Dr. Garry Sunter, Voting
Mr. Phillip Vaughan, Voting
Mr. Brian Moroney, Non-Voting
Dr. James MacMillan, Non-Voting

Members Not Present: Dr. Jilani Chaudry, Voting
Ms. Wendy McCoy, Non-Voting
Ms. Barbara Rodela, Non-Voting

Minutes Recorded By: Ms. MaryLou Spillers

Meeting called to order at 9:15 a.m.

I. Approval of Institutional Biosafety Committee Minutes date 08-23-05. Approved

II. Introduction

Dr. Lopez-Ribot asked everyone to introduce themselves and then he read the tasks/duties/responsibilities of the committee to the members.

III. Discussion

There were questions regarding the procedures for packaging and shipping of biohazardous materials. Mr. Moroney said he would be glad to train on an individual basis as needed, but that he will look into holding training classes for the PI's and their staff.

It was discussed and agreed that Dr. Lopez-Ribot and Wendy would be the preliminary reviewers for the applications. This will eliminate the need for lengthy meetings.

It was also discussed that meetings may not need to be held every month. Perhaps on months where there are no protocols to review. When there are protocols with minor/simple procedures, communication between the committee members could take place via telephone and/or e-mail to expedite their approval.

IV. New Business

A question for you as the Director, "Is it possible to request a separate drive for the submission of the protocols?" This will eliminate paperwork and the possibility of a closed Inbox – which was the case with some of the members.

It was agreed that IBC meetings be held on the 1st Tuesday of every month at 9:00 a.m. The location is yet to be determined, but everyone likes the Tobin Bldg. Conference Room.

V. Protocol Reviews:

New Protocol #B24 - "Genetic Analysis of *Borrelia burgdorferi* Lp54 loci"

- 1) Dr. Lopez-Ribot volunteered to contact Dr. Seshu regarding those minor clarifications before giving the final approval.

Tentatively approved pending minor modifications— email notification to PI

New Protocol #B25 - "Comprehensive analysis of *Cryptococcus neoformans* pathogenesis"

Approved - email notification to PI

VI. OLD BUSINESS:

N/A

VII. Ajourn:

Meeting adjourned at 11:00 a.m. The next meeting is scheduled for Tuesday, December 6, 2005 at 9:00 a.m.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Tuesday, January 3, 2006, Tobin Building, Conference Room # 1.102

Members Present: Dr. Jose Lopez-Ribot, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Jilani Chaudry, Voting
Dr. Garry Sunter, Voting
Ms. Wendy McCoy, Non-Voting
Mr. Brian Moroney, Non-Voting
Dr. James MacMillan, Non-Voting
Ms. Barbara Rodela, Non-Voting

Members Not Present: Dr. Karl Klose, Voting
Dr. Teresa Quitugua, Voting
Mr. Phillip Vaughan, Voting

Minutes Recorded By: Ms. Suzette Vallejo, IBC Coordinator

Meeting called to order at 9:00 a.m.

- I. A motion was made and seconded to approve as circulated the minutes of the IBC meeting on November 1, 2005. The motion carried unanimously.

II. **Discussion**

Discuss situation with autoclaves in different buildings and progress on changing the way UTSA handles biohazard waste (after meeting with administrators).

One of the committee members pointed out the situation with autoclaves and the steam generator in the Bioscience building. It appears that the autoclave situation has been an issue for a few years now. Also, the Margaret Tobin building has only one autoclave outside the BSL3. The same committee member mentioned that a special meeting took place with administrators to discuss the situation with autoclaves. The main focus of the meeting was to try to change the ways UTSA handles biohazard waste.

Action: The Chairman to compose a follow-up memo explaining an urgent crisis with respect to the situation with autoclaves in different buildings.

III. **New Business**

One committee member has brought to IBC attention, that some of the laboratories will be facing a potential issue with respect to not having an adequate number of cold storage facilities. There is a potential measure that might be considered to address this storage facilities issue.

- Provide the laboratories in BSB with Stericycle boxes. Stericycle would provide the boxes, liners, transport cost and the labor. The principle investigators or laboratory coordinators would have to pack the boxes up and put them in a designated place where Stericycle can pick them up.

One committee member mentioned that the Margaret Batts Tobin Laboratory building has one autoclave for potentially eighty people. Also, the BSE does not have an autoclave on the 3rd floor. This is completely unacceptable.

Action: The Chairman to compose a memo explaining an impending crisis with respect to not having an adequate number of autoclaves in the Margaret Batts Tobin laboratory building and the Biotechnology, Sciences and Engineering building.

IV. Discuss one committee member's idea for a mandatory IBC survey to be submitted with grants in order to identify users who need to submit a biosafety protocol.

One committee member said the idea is to have the researcher submit a survey with every grant proposal. It is imperative that all principle investigators or lab coordinators complete the survey. The information supplied will help the IBC maintain compliance with federal regulations. Faculty will be prohibited from submitting any kind of grant application without a current copy of this survey on file. All principle investigators or lab coordinators must indicate whether their IBC applications are pending, whether their projects are exempt by NIH/IBC guidelines, or whether their research does not utilize recombinant DNA, infectious agents, toxins or vertebrate tissues that could be potentially infectious. The Biosafety Survey would benefit the researcher.

A memo from the Vice President for Research stated that in order to accurately assess the use of these materials at UTSA it is mandatory that all laboratory coordinators or principle investigators immediately submit the Biosafety Survey whether they do or do not use infectious agents, recombinant DNA or vertebrate tissue.

Approval of experimental protocols is the responsibility of the laboratory coordinator or the principle investigator. The Biosafety Survey is a method used to identify users who have not submitted a Biosafety protocol. The Biological Safety Officer conducts laboratory inspections on an annual basis. The Biosafety checklist form is a method used to cross reference an approved protocol.

The Institutional Biosafety Committee reviewed the Biosafety Survey form. The IBC suggested minor changes and that the final text be reviewed by IBC. An update will be given at the next IBC meeting.

V. Protocol Reviews

No new protocols to review this month.

VI. Old Business

N/A

VII. Adjourn

Meeting adjourned at 11:00 a.m. The next meeting is scheduled for Tuesday, February 7, 2006 at 9:00 a.m.

MINUTES

Institutional Biosafety Committee Meeting

The University of Texas at San Antonio

Tuesday, February 7, 2006, Tobin Building, Conference Room #
1.102

Members Present: Dr. Jose Lopez-Ribot, Chair, Voting
Dr. Bernard Arulanandam, Voting
Dr. Karl Klose, Voting
Dr. Teresa Quitugua, Voting
Dr. Garry Sunter, Voting
Ms. Wendy McCoy, Non-Voting
Mr. Brian Moroney, Non-Voting
Dr. James MacMillan, Non-Voting
Mr. Phillip Vaughan, Voting

Members Not Present:

Dr. Jilani Chaudry, Voting
Ms. Barbara Rodela, Non-Voting

Minutes Recorded By: Ms. Suzette Vallejo, IBC Coordinator

Meeting called to order at 9:00 a.m.

I. Approve minutes from the previous meeting

A motion was made and seconded to approve the minutes of the IBC meeting of January 3, 2006 with stipulations. Move to Approve, Dr. Klose; Second, Dr. Sunter. The motion carried unanimously.

II. New Protocol for review/discussion

New Protocol # B26: "Isolation of Nuclei from HEK 293 and HeLa Cells"

A motion was made and seconded to approve as submitted.
6 in favor of the motion, 0 opposed, 0 abstained

New Protocol # B27: "Human feces collection for the identification of normal flora of the lower intestinal tract"

- a) It is recommended that the principle investigator transport any potential hazardous materials in an appropriate, sealed primary container, and that container secured in an appropriate secondary container.

A motion was made and seconded to approve the protocol when the above stipulations have been met:

6 in favor of the motion, 0 opposed, 0 abstained

III. Old Business

Update on situation and progress with autoclaves in different buildings

One committee member reported that the situation in the BSB has been pretty much taken care of. Another committee member stated that in the BSB they are supposed to connect the main steam. This project is well underway. Another committee member mentioned that the situation with autoclave in the Margaret Batt Tobin building is underway. He also stated that there are some plans to install an autoclave on the third floor of the BSE.

One of the committee members informed the IBC that a position of Safety Technician was approved on February 6, 2006.

Action: The Chairman will follow-up on situation with autoclave on the third floor of the BSB.

IV. New Business

There was a discussion on whether the IBC should potentially approve an umbrella protocol that covers regular experiments conducted at Brooks City-Base. One of the committee members was assured that the experiments would not involve the Biosafety Level 3. The experiments would involve routine microbiology, cell line, and maybe some PCR procedures. IBC approval will be granted for experiments that consist of only Biosafety Level 1 and Biosafety Level 2.

It was discussed and agreed that the IBC committee would approve an umbrella protocol based on the following stipulations:

- a) Approval letter from Brooks City-Base Biosafety Committee is required to be submitted to the IBC.
- b) Ensure that research is implemented as specified in the IBC approved protocol and any modifications must be approved in advance by the UTSA IBC.
- c) The Chairman volunteered to contact the PI at Brooks City-Base regarding those minor modifications before giving the final approval.

IV. More discussion on the "mandatory" survey as suggested before by one of the committee members

One of the committee members mentioned that he will ask the new Vice President for Research to issue a memo in regards to the "mandatory" survey.

VI. Ajourn

Meeting adjourned at 10:00 a.m. The next meeting is scheduled for Tuesday,
March 7, 2006 at 9:00 a.m.