


To: "'Johnson, Michelle \(\text{NIH/OD}\) [C]'" <johnsom1@od.nih.gov>
From: Edward Hammond <hammond@sunshine-project.org>
Subject: University of Texas Arlington
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>,
ward@uta.edu
Bcc:
Attachments:  UNIVTEXASARLINGTON.pdf

Dear Ms. Johnson:

I have recieved the attached correspondence from the University of Texas at Arlington.

Here we have yet another case of a dysfunctional IBC / University bureaucracy that would rather generate lengthy legalistic correspondence and a pain for everyone than to simply hit the e-mail "forward" button to send a request for IBC minutes to the appropriate individual. It was well within Ms. Morningstar's power to do so - indeed, it would have been easier; but oh, no!, at the University of Texas at Arlington, they like to do things the hard and senseless way.

And of course they could have just sent the minutes to me in response to your letter, and that would likely have been the end of the matter; but oh, no! I'll bet this attitude will bleed through and, when everything is said and done, they will actually detail somebody to write me a letter and request a payment of \$1.12 or some other trivial amount the collection of which will obviously cost the University far more than the dollar or two of "income" that it produces.

I acknowledge the e-mail print out that UTA sent with its reply, however, I have carefully reviewed my e-mail from 19 October and I cannot find anything from Ms. Morningstar. As OBA knows, when cases like this surface, I am certainly willing to admit it if it turns out that I missed an incoming mail. In this case, however, I never recieved Ms. Morningstar's reply. Of course, the question is really moot because UTA could have resolved the issue by handling the request properly in the first place and honoring its obligations under the NIH Guidelines. It certainly should know by now that I am not going to drop a request if they don't reply, so they should have seen this coming.

Nobody, it seems, could ever accuse the University of Texas at Arlington of being plagued by common sense.

My request was sent to the person and address indicated as the contact for the IBC in records provided to me by NIH OBA. That is, I used OBA's own information for the IBC contact. While I am familar with Texas law, I am also familiar with the Public Access Provisions of the NIH Guidelines, which do not require me to dig around for a public information officer at every institution with and IBC and for me to have a better record than NIH of the request preferences of every little vo-tech and state college like UTA in the country.

In view of the above, I believe that the fundamental problem here is between OBA and UT System. You two should work out how to handle this. That problem, however, should not impinge upon the right of any of the member of the public to recieve UTA's IBC minutes, an obligation of UTA that it has thus far failed to honor.

Accordingly, I maintain that due to dischord between UTA and OBA, and

UTA's idiotic intransigence about refusing to process the request that it acknowledges receiving, that UTA remains in noncompliance with the NIH Guidelines.

Note that I am copying this to Mr. Ward. One can hope that UTA will now finally construe this as a valid request pursuant to the NIH Guidelines; but I certainly submit that NIH should have no tolerance for UTA's wasteful shenanigans. This problem would never have existed if UTA demonstrated the slightest common sense.

Sincerely,

Edward Hammond



THE UNIVERSITY
OF TEXAS
AT ARLINGTON

Office of Accounting
and Business Services

Box 19136

219 W. Main Street

Arlington, Texas

76019-0136

T 817.272.2194

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oabs@uta.edu

March 9, 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 Arlington

Dear Ms. Johnson-Lancaster:

On February 26, 2007, the University of Texas at Arlington ("University" or U. T. Arlington) 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 hand-dated "12 October 2006" and faxed to (817) 303-9187, ¹ the requested IBC minutes were not provided to him because the inquiry was not submitted to the University's designated Public Information Officer, as required by the Texas Public Information Act ("TPIA").

In this instance, Mr. Hammond faxed his request directly to the University's Office of Research Integrity and Compliance ("RIC") on October 12, 2006 (TAB 1). This inquiry was not submitted in accordance with Section 301(c), *Texas Government Code*, which states the following:

"...a written request includes a request made in writing that is sent to the officer for public information, or the person designated by that officer, by electronic mail or facsimile transmission."

¹ We note that the NIH did not send a copy of the specific request at issue with this notice of complaint. We assume then that because the notice was sent to Kirstin Morningstar at P.O. Box 19188, and Ms. Morningstar received and responded to one inquiry from Mr. Hammond in 2006, this is the precise request at issue. 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 8, 2007

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Although not a requirement of law, on October 19, 2006, Research Manager Kirstin Morningstar replied in good faith to the Sunshine Project, via email. Ms. Morningstar advised the Sunshine Project that requests for information must be submitted to the University's Public Information Officer. In that email she also provided the contact information for the University's Public Information Officer (**TAB 2**).

Since Mr. Hammond did not submit his inquiry to U. T. Arlington's "*officer for public information*," nor the "*person designated by that officer*," his fax to RIC did not trigger the applicable deadlines imposed by TPIA. Further, despite having received a reply from RIC, Mr. Hammond never re-submitted his inquiry to the Public Information Officer; therefore, the University had no duty to respond and Mr. Hammond's inquiry went unanswered

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. 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 TPIA is the mechanism by which the public has access to government documents, including IBC minutes. There is no separate process utilized for NIH documents.

In addition to providing a response framework, if a requestor seeks documents that have exceptions to disclosure, the request must be handled pursuant to TPIA to establish jurisdiction.

As the arbiter in open record disputes, the Texas Attorney General has the authority to rule on the public or non-public nature of requested information. However, this authority can only be exercised when the Attorney General has jurisdiction to do so. Only requests that are submitted pursuant to TPIA establish this jurisdiction and trigger the deadlines imposed by law.

Your office has recognized and affirmed the fact that in some instances information contained in IBC minutes may need to be withheld from disclosure. 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)

March 8, 2007

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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 insistence, indeed the requirement, that Mr. Hammond submit his inquiry so as to trigger TPIA is 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 Sunshine Project has been submitting requests for information to University of Texas System campuses for years; these requirements of law are not unfamiliar to Mr. Hammond. Specific to this request, Mr. Hammond failed to comply with the requirements of TPIA when requesting access to public information; therefore, he was not due a response.

The NIH has repeatedly indicated that requiring a requestor to adhere to a standard process for accessing documents is *not* a violation of the NIH guidelines. The University cannot violate NIH guidelines when, as in this instance, a requestor refuses to comply with the established process and consequently does not receive a reply to his inquiry.

If at this time Mr. Hammond still requires a response to his inquiry, he need simply submit his request me the University's Public Information Officer, Mr. Rusty Ward. I will again provide my contact information below:

By Mail:

Mr. Rusty Ward
Vice President for Business Affairs
The University of Texas at Arlington
P.O. Box 19136 Arlington, Texas 76019-0136

By Electronic Mail: ward@uta.edu

By Fax: (817) 272-2136

Full contact information for all the University of Texas System campuses can be found online at the following link: http://www.utsystem.edu/ogc/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 comply with the established and standardized processes provided in Texas law for access to information. All requestors seeking access to University documents adhere to these same procedures without issue. The University can only advise the requestor how to access the information he seeks; we cannot force him to comply. However, if he refuses to comply and subsequently receives no response, 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.

March 8, 2007

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If you need additional information, please do not hesitate to contact me at (817) 272-2194.

Sincerely,



Rusty Ward

Vice President for Business Services and Controller
The University of Texas at Arlington



Enclosures

cc: Edward Hammond

From: Morningstar, Kirstin C
Sent: Thursday, October 19, 2006 4:58 PM
To: 'hammond@sunshine-project.org'; 'tsp@sunshine-project.org'
Subject: The Sunshine Project / The University of Texas at Arlington IBC Minutes

Dear Mr. Hammond,

The University of Texas at Arlington Office of Research Integrity and Compliance received a request from The Sunshine Project on October 12, 2006 requesting minutes of UTA's Institutional Biosafety Committee.

However, all requests for records from the University of Texas at Arlington should be submitted directly to the **Custodian of Records** at UTA, as listed here:

Mr. Rusty Ward

Vice President for Business Services & Controller

Custodian of Records

PO Box 19136

Arlington, TX 76019

FAX 817-272-0839

ward@uta.edu

Records requests must be in writing and will be accepted by the Custodian of Records via mail, fax or e-mail. **A request sent to anyone at UTA other than the Custodian of Records is not a valid request.**

Thank you,

Kirstin Morningstar

Research Compliance Manager
Office of Research Integrity & Compliance

Box 19188 Arlington, TX 76019
P: (817) 272-1234, (817) 272-3723
Fax: (817) 272-1111
Arlington Technology Incubator (ATI)
202 E. Border, Suite 201



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985
(301) 496-9838 (Phone)
(301) 496-9839 (Fax)
<http://www4.od.nih.gov/oba/>

February 20, 2007

Kirstin Morningstar, B.S.
Research Compliance Manager
University of Texas at Arlington
Office of Research and Integrity and Compliance
Box 19188, 202 E. Border
Arlington, TX 76019-0188

Dear Ms. Morningstar:

The NIH Office of Biotechnology Activities (OBA) has received a complaint from the Sunshine Project that University of Texas at Arlington has been unresponsive to a 2006 request for copies of your institution's Institutional Biosafety Committee (IBC) meeting minutes.

Section IV-B-2-a-(7) of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* states:

Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.

To explore the facts pertinent to this complaint, we ask that University of Texas at Arlington provide within 30 days of receipt of this letter a written response that indicates whether University of Texas at Arlington received a request in 2006 for its IBC meeting minutes from the Sunshine Project. If your institution did receive such a request, please indicate whether the minutes have been provided.

- If so, please send to our office a copy of the materials that were provided to the Sunshine Project along with a copy of the original cover letter or other documentation of the date these materials were provided.
- If the IBC minutes have not been provided, please include in your response information explaining why the minutes have not yet been provided and indicate the timeframe within which you anticipate sending these materials to the Sunshine Project. When the request is fulfilled, please send to OBA a copy of your communication to the Sunshine Project.

FEB 26 2007

Kirstin Morningstar, B.S.
February 20, 2007
Page 2

Further information regarding public access to IBC minutes can be found on the OBA Web site at: http://www4.od.nih.gov/oba/IBC/IBC_Minute_Q_A.pdf. If you have any questions about requirements under the *NIH Guidelines*, you may contact OBA staff at oba@od.nih.gov or by phone at 301-496-9838. **All materials responsive to this letter should be sent to the attention of Michelle Johnson-Lancaster, IBC Coordinator, at the address on the letterhead.**

Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Amy P. Patterson', with a long horizontal flourish extending to the right.

Amy P. Patterson, M.D.
Director

cc: Liping Tang, Ph.D., Institutional Biosafety Committee Chair
Lana Skirboll, Ph.D., Director, NIH Office of Science Policy
Valerie Bonham, J.D., Office of General Counsel, NIH
Norka Ruiz Bravo, Ph.D., NIH Deputy Director for Extramural Research
Joseph Ellis, Acting Director, NIH Office of Policy for Extramural Research Administration
Allan C. Shipp, Director of Outreach, NIH Office of Biotechnology Activities
Edward Hammond, Director, Sunshine Project



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April 17, 2007

Mr. Edward Hammond
The Sunshine Project
1920 Stuart Street
Berkeley, CA 94703

Dear Mr. Hammond:

Enclosed are the records that you requested from The University of Texas at Arlington. Please let me know if I can be of further assistance.

Sincerely,

Rusty Ward
Vice President for Business Services and Controller
The University of Texas at Arlington



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IBC convened at 3:00 pm on November 1, 2006 in the Conference Room 215 of the Office of Research Integrity & Compliance, 202 E. Border.

Attending Members:

Dr. Liping Tang	Associate Professor, Bioengineering	IBC Chair / rDNA Expert / Animal Expert
Dr. Michael Roner	Assistant Professor, Biology	Vice-Chair / rDNA Expert / Animal Expert
Ms. Laura Warren	Environmental Health & Safety	Lab Safety
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Ms. Viola Ohr	Laboratory Analyst, City of Arlington	Non-Affiliated Member
Mr. Stephen Harper	Assistant Director Support Services, City of Arlington	Non-Affiliated Member

Absent Members:

Dr. John Bacon	Professor, Biology	Plant Expert
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
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1. Review and Approval of Meeting Minutes:

- The minutes from the October 4, 2006 meeting were presented for review and discussion.

The Committee voted unanimously to approve the minutes as presented.

2. Annual Reports / Amendments for Review:

❖ Dr. Cedric Feschotte: IBC Protocol #IBC06.001

Transformation of E. coli

- Dr. Tang said he did not see any major changes in the research, besides a change in personnel.
- Ms. Morningstar said everyone's training is up to date.
- Ms. Morningstar said that the NIH has released new information regarding E. coli, and many strains have been moved to Biosafety Level (BSL) 1. She said the protocol was originally approved as BSL-II, but that it may need to be reassessed. Dr. Roner said the PI is using K12 as listed on the new information, so it can be classified as BSL-I. Ms. Morningstar said she would notify the PI of the change and also, that the IBC protocol itself is still required due to Dr. Feschotte's rDNA work.

The IBC voted unanimously to approve the Annual Report and the Amendment. The IBC also voted unanimously to downgrade the laboratory from Biosafety Level II to Biosafety Level I.

❖ Dr. Michael Roner: IBC Protocol #IBC04.001

HIV Antiviral Testing

- Ms. Warren asked if that after this amendment for deletion of personnel, if there will be any other students working on this protocol. Dr. Roner said no, there will be no students.

The IBC voted to approve the Annual Report and the Amendment. Dr. Roner abstained from the vote.

The University of Texas
ARLINGTON[™]

3. Annual Report for Review:

❖ **Dr. Elena de la Casa-Esperon: IBC Protocol #IBC06.005**

Study of the Chromatin Properties of the Om Region and of an X-Linked Gene Involved in the Control of Meiotic Recombination in a Mouse

- Mr. Harper asked about the PI's radiation approval. Dr. Roner said when she originally submitted the IBC protocol, she may not have had the radiation approval yet. Ms. Morningstar said she can get a copy of her radiation approval letter from EH&S and attach it to the protocol.

The IBC voted unanimously to approve the Annual Report.

4. Amendment for Review:

❖ **Dr. Andre Pires da Silva: IBC Protocol #IBC06.004**

The Study of Regulatory Genes that Control Embryonic Development and Neurodegeneration

- Dr. Tang said the funding needs to be added to Section B.
- Ms. Morningstar asked if the new personnel on the amendment have received training. Ms. Warren said yes, it is complete.
- Ms. Morningstar explained that originally, Dr. Pires da Silva had planned to do human cell culture work along with his rDNA work. However, Dr. Pires da Silva has partnered with Dr. Subhrangsu Mandal, and Dr. Mandal will perform the cell culture work for him under his own currently approved protocol. So, Dr. Pires da Silva's protocol will remain classified as Biosafety Level 1.

The IBC voted unanimously to approve the Amendment pending the minor modifications requested.

5. New Business / Announcements:

- Annual Reports: Ms. Morningstar asked the Committee if there was any additional information they felt they needed to conduct a thorough annual review of a protocol. The Committee requested that an updated floor plan be attached to each annual report, in case there is new equipment or items have moved in the laboratory.
- IBC Annual Select Agent Surveys: Ms. Morningstar announced that she will be sending out the annual select agent surveys in January to be completed by researchers in Biology, Chemistry, and Bioengineering.

6. Adjourn:

The meeting adjourned at 4:00 pm.



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IBC convened at 3:00 pm on October 4, 2006 in the Conference Room 215 of the Office of Research Integrity & Compliance, 202 E. Border.

Attending Members:

Dr. Liping Tang	Associate Professor, Bioengineering	IBC Chair / rDNA Expert / Animal Expert
Dr. Michael Roner	Assistant Professor, Biology	Vice-Chair / rDNA Expert / Animal Expert
Ms. Laura Warren	Environmental Health & Safety	Lab Safety
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert
Mr. Stephen Harper	Director Support Services, City of Arlington	Non-Affiliated Member

Absent Members:

Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Dr. John Bacon	Professor, Biology	Plant Expert
Ms. Viola Ohr	Water Quality Technician, City of Arlington	Non-Affiliated Member
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
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1. Review and Approval of Meeting Minutes:

- The minutes from the July 5, 2006 meeting were presented for review and discussion.

The Committee voted unanimously to approve the minutes as presented.

2. New Protocol for Review:

❖ **Dr. Subhrangsu Mandal: IBC Protocol #IBC07.001**

Functions of Histone Methylation in Gene Expression / Transfection of Histone Methylases Set1/Ash2

- Mr. Harper asked if this person was faculty at UTA; Ms. Morningstar said yes, he is a new faculty member.
- Mr. Harper said he cannot fully understand the paragraph in item #9. Dr. Tang said the PI should simplify it and revise it in layman's terms.
- Mr. Harper said that table 5 and PPE is not consistent – it states that there is no explosion hazard, but they will be working with flammable, compressed gases. Additionally, Mr. Harper pointed out that one part of the protocol states they will not use chemical volumes greater than 1L, but the protocol later states they will have 3L of chemical.
- Dr. Tang asked about the rooms listed, room 310 and room 316. Dr. Roner said room 310 is the cell culture room that he will be using. Dr. Tang asked if a laboratory safety notebook has to be located in every room they work in. Ms. Warren stated no, as long as it is accessible and all the lab personnel know where to obtain it.
- Dr. Tang said the PI needs to fill in the blanks in Attachment D for recombinant DNA.
- Dr. Roner said a copy is needed of the approved radiation protocol.
- Ms. Morningstar asked about the status of training. Ms. Warren said all personnel need blood borne pathogen training and hazard communication training.
- Ms. Morningstar asked if the laboratory met all safety standards; Ms. Warren said yes.

The IBC voted unanimously to approve the protocol pending the minor modifications and completion of the training requirements.

3. Amendment for Review:

❖ **Dr. Carl Lovely: IBC Protocol #IBC06.002**

Disk Diffusion Antibiotic Susceptibility Testing of Mycobacterium smegmatis

- Ms. Morningstar said the amendment was for addition of personnel. Ms. Warren said she would verify their completion of training.

The IBC voted unanimously to approve the amendment pending the completion and verification of training requirements.

4. New Business / Announcements:

- No new business or announcements.

5. Adjourn:

The meeting adjourned at 3:30 pm.



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IBC convened at 3:00 pm on July 5, 2006 in the Conference Room 215 of the Office of Research Integrity & Compliance, 202 E. Border.

Attending Members:

Dr. Liping Tang	Associate Professor, Bioengineering	IBC Chair / rDNA Expert / Animal Expert
Dr. Michael Roner	Assistant Professor, Biology	Vice-Chair / rDNA Expert / Animal Expert
Ms. Viola Ohr	Water Quality Technician, City of Arlington	Non-Affiliated Member
Ms. Laura Warren	Environmental Health & Safety	Lab Safety
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert
Dr. John Bacon	Professor, Biology	Plant Expert
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety

Absent Members:

Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Mr. Stephen Harper	Director Support Services, City of Arlington	Non-Affiliated Member

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
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1. Review and Approval of Meeting Minutes:

- The minutes from the June 7, 2006 meeting were presented for review and discussion.

The Committee voted unanimously to approve the minutes as presented.

2. New Protocols for Review:

❖ **Dr. Sanjay Awasthi / Dr. Sharad Singhal: IBC Protocol #IBC06.008** *Transfection of RLIP76/RALBP1*

- Dr. Tang said that item #9 should be in layman's terms. Also, Dr. Tang pointed out that in Part II, table 2 is incomplete and that table 5 should include more information regarding hazards. Ms. Ohr said she would like to see more information regarding PPE (personal protective equipment).
- Dr. Bacon asked about the radioactive material mentioned in the protocol. Ms. Morningstar said a copy of the approved radiation protocol is attached to their biosafety application.
- Ms. Morningstar asked Ms. Warren if their lab space had passed inspection. Ms. Warren said not yet, the biosafety cabinet must be certified. Ms. Warren said she would also check on the status of the bloodborne pathogen training for all protocol personnel.

The IBC voted unanimously to approve the protocol pending the addition of hazard and PPE information to the protocol, completion of bloodborne pathogen training by all protocol personnel, and successful completion of a laboratory inspection.

❖ **Dr. Thomas Chrzanowski: IBC Protocol #IBC06.009** *Biological Biofilms*



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IACUC convened at 3:00 pm on June 7, 2006 in the Conference Room 218 of the Office of Research Integrity & Compliance, 202 E. Border.

Attending Members:

Dr. Michael Roner	Assistant Professor, Biology	Vice-Chair / rDNA Expert / Animal Expert
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Ms. Viola Ohr	Water Quality Technician, City of Arlington	Non-Affiliated Member
Mr. Stephen Harper	Director Support Services, City of Arlington	Non-Affiliated Member
Ms. Laura Warren	Environmental Health & Safety	Lab Safety
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert

Absent Members:

Dr. Liping Tang	Associate Professor, Bioengineering	IBC Chair / rDNA Expert / Animal Expert
Dr. John Bacon	Professor, Biology	Plant Expert
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
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1. Review and Approval of Meeting Minutes:

- The minutes from the April 12, 2006 meetings were presented for review and discussion.

M/S/P *The Committee voted unanimously to approve the minutes as presented.*

2. Amendment for Review:

❖ **Dr. Andre Pires da Silva: IBC Protocol #IBC06.004**

The Study of Regulatory Genes that Control Embryonic Development and Neurodegeneration

- Dr. Roner said he noticed a few deficiencies: a floor plan of the lab is needed, an inspection of the lab space is needed, and the PI should provide a description of what he is going to transport.
- Ms. Morningstar asked if any restrictions or safeguards should be required for the transport. Dr. Roner said no, he did not mind if they transport them as long as they are contained and it is clear what he will be transporting (cells, samples, etc.).
- Ms. Warren asked if the PI mentioned why he is not doing this in his own lab. Dr. Roner said the PI does not have a cell culture facility and there is no space in his own lab. Dr. Roner said the cell culture facility was supposed to be set up as a central facility for everyone to use. Ms. Warren said the lab she inspected today was not the one listed on his protocol; he had directed her to a different lab.
- Mr. Sims asked what kind of containment would be necessary for transporting materials. Dr. Roner said the PI just needs secondary containment with probably some absorbent paper.
- Mr. Harper pointed out that under the hazardous chemical list the PI states that he has 5L of flammable chemicals, but also states that there is no explosive risk. Ms. Warren said she would take a look at that when she inspects the lab.

The IBC voted unanimously to approve the amendment pending the submission of a floor plan, transportation procedures, and a lab inspection by the EH&S office.



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IACUC convened at 3:00 pm on April 12, 2006 in the Conference Room 218 of the Office of Research Integrity & Compliance, 202 E. Border.

Attending Members:

Dr. Liping Tang	Associate Professor, Bioengineering	IBC Chair / rDNA Expert / Animal Expert
Dr. Michael Roner	Assistant Professor, Biology	Vice-Chair / rDNA Expert / Animal Expert
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Dr. Liping Tang	Associate Professor, Bioengineering	Animal Expert
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety
Dr. John Bacon	Professor, Biology	Plant Expert
Ms. Viola Ohr	Water Quality Technician, City of Arlington	Non-Affiliated Member

Absent Members:

Mr. Stephen Harper	Director Support Services, City of Arlington	Non-Affiliated Member
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
Ms. Laura Simoneaux	Environmental Health & Safety	Biological Safety Specialist

1. Review and Approval of Meeting Minutes:

- The minutes from the March 8, 2006 meetings were presented for review and discussion.

M/S/P *The Committee voted unanimously to approve the minutes as presented.*

2. Annual Report and Amendment for Review:

❖ **Dr. Esther Betran: IBC Protocol #IBC04.003** *E. Coli Transformation and Drosophila Transformation*

- Dr. Tang asked if there were any changes to the protocol. Ms. Morningstar said the only change was to add new personnel.
- Ms. Morningstar asked Ms. Simoneaux if the new personnel have completed Hazard Communication training yet. Dr. Bacon asked if HazCom training has to be taken every year. Mr. Powell said ordinarily not, unless there is a change or problems in the lab. Mr. Powell said there is a new HazCom training offered however that everyone must complete once. He asked Ms. Simoneaux to contact the individuals to set up their training.

The Committee voted unanimously to approve the annual report. The Committee also voted unanimously to approve the amendment pending the new personnel's completion of the required Hazard Communication training.

3. New Business / Announcements:

- Dr. Tang inquired about the requirements to call a full board meeting for review of annual reports and amendments. Ms. Morningstar said she had reviewed the possibilities, but the regulations do not indicate any other type of allowable review other than a full review by the Committee. She said for animal research, designated review is explained and allowed, and for human subject research, expedited review is allowed. She said there is no indication of any other type of review like this for research reviewed by the IBC. Ms. Morningstar said she would look into it further to find if there is another way to process and review these items.

4. Adjourn:

The meeting adjourned at 3:20 pm.



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IACUC convened at 3:00 pm on March 8, 2006 in the Conference Room 218 of the Office of Research Integrity & Compliance, 202 E. Border.

Attending Members:

Dr. Lorraine van Waasbergen	Assistant Professor, Biology	IBC Chair / rDNA Expert
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Mr. Stephen Harper	Director Support Services, City of Arlington	Non-Affiliated Member
Dr. Liping Tang	Associate Professor, Bioengineering	Animal Expert
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert

Absent Members:

Dr. John Bacon	Professor, Biology	Plant Expert
Dr. Michael Roner	Assistant Professor, Biology	Vice-Chair / rDNA Expert / Animal Expert
Ms. Viola Ohr	Water Quality Technician, City of Arlington	Non-Affiliated Member

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
Ms. Laura Simoneaux	Environmental Health & Safety	Biological Safety Specialist

1. Review and Approval of Meeting Minutes:

- The minutes from the December 6, 2005 and the March 1, 2006 meetings were presented for review and discussion.

M/S/P *The Committee voted unanimously to approve the minutes from both meetings.*

2. Protocols for Review:

❖ **Ms. Debra Wawro: IBC Protocol #IBC06.006**

Staphylococcus aureus Binding

- Dr. van Waasbergen said that Ms. Wawro claims that she has had microbiology training and that she ran a laboratory. Dr. van Waasbergen said that is not true, that Ms. Wawro did biofilm work on a cochlear implant; she has not worked directly with the transfer of microbes. Dr. van Waasbergen said she kept pressing Ms. Wawro for details to assess her level of knowledge, until it became clear that her knowledge is lacking.
- Dr. Tang said he would agree to help Ms. Wawro. He said that staphylococcus aureus is not very dangerous, but the problem is that the protocol is lacking certain details. Dr. Tang pointed out that for instance, nobody grows bacteria at room temperature overnight or decontaminates everything with an autoclave. Dr. Tang said he could train her, but from the Committee standpoint, she needs a faculty sponsor.
- Dr. van Waasbergen said maybe it could be arranged that someone do a dummy run of her procedures to make sure she knows what she is doing. Dr. Tang said another suggestion would be to use staphylococcus epidermis, which is on everyone's skin and is less dangerous.

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- Dr. van Waasbergen pointed out that Ms. Wawro listed a collaboration with Dr. Chrzanowski – maybe Dr. Tang or someone from Dr. Chrzanowski's lab could help her, if she would be agreeable to having outside help. Dr. van Waasbergen said she would feel more comfortable if there was faculty oversight.
- Ms. Simoneaux said that Ms. Wawro mentioned Dr. Geoffrey Grant from ATI serving in this purpose, he is a bacteriologist. Dr. van Waasbergen said she reviewed Dr. Grant's resume, and he's not, plus he's busy as director of ATI.
- Mr. Powell said that this oversight would not be necessary forever, just for a limited time until the Committee feels comfortable with her procedures. He said Ms. Simoneaux could observe as well, that way there is another set of eyes and she could provide assistance down the road.
- Ms. Simoneaux said that Ms. Wawro's student, Shelby Zimmerman, seems to be well-educated in this area. Dr. van Waasbergen said that she has not had anything to do with live microbes, that she can see.
- Dr. van Waasbergen said that the autoclave information is not in the protocol. Ms. Simoneaux said that she went over and inspected the lab, and it is pristine – they already had all the proper autoclave materials. Dr. van Waasbergen asked if the guidelines for autoclaves are in the Laboratory Safety Manual. Ms. Morningstar said yes, plus they are in the UTA Biosafety Manual.
- Dr. van Waasbergen asked Ms. Simoneaux if she had bacteriology knowledge, and would she be willing to help Ms. Wawro. Ms. Simoneaux said yes, and that she would be glad to help. Mr. Powell said if Dr. Tang goes through a run-through of the procedures with Ms. Wawro, Ms. Simoneaux can attend to establish a comfort level, then Ms. Simoneaux can provide additional oversight.
- Dr. van Waasbergen said that she feels the Office of General Counsel (OGC) should be consulted regarding the liability of this situation, since Ms. Wawro is not a UTA employee. Mr. Powell said that in his opinion, the Committee has properly done what they are charged with doing, in making sure the procedures are performed safely. He said he feels the Committee should move forward with what was discussed with the additional oversight to the project.
- Dr. van Waasbergen said she would feel more comfortable with Dr. Grant as a faculty sponsor; she said he is actually a faculty member of the Biology department. Mr. Powell said that it seems like a practical approach that is workable for both the researcher and the University.
- Dr. van Waasbergen asked about consulting OGC. Ms. Morningstar said that it is a decision that will need to come from Dr. Ronald Elsenbaumer, as VP for Research and the responsible person for ATI. She said that Pat Myrick will be speaking to him about the issue.
- Dr. van Waasbergen said that in the protocol, an autoclave should be listed under handling hot/cold materials (table 5). She also pointed out that location of hazards is missing in Table 4, and said it would be helpful to reiterate what she will do in the event of a spill for her specific volume size. Dr. van Waasbergen also pointed out that Attachment C lists a biosafety cabinet, but she does not have one in her lab, and under Emergency Procedures she lists how to clean a spill, but the procedures are incorrect according to the Lab Safety Manual.
- Mr. Harper pointed out that in Attachment A, it lists combustible and flammable materials, but under Personal Protection, it says there are no explosion hazards – this seems to be contradictory. He said that 38L of flammable chemicals are listed. Mr. Powell said that might be more than what she is allowed to store in that small room, and they would have to look at that. He said that depending on how much she has, it would be flammable but maybe not explosive. Dr. Tang asked if there was a fume hood available in the room. Ms. Simoneaux said there is not – she asked Ms. Wawro about it today, and Ms. Wawro said all she has is 70% ethanol. Dr. Tang asked if she needs chemical hood for that. Mr. Powell said this lab is not really meant for this use, and he especially does not like the fact that the sink is located in a different room. Mr. Powell asked if there was a flammable storage cabinet in the lab; Ms. Simoneaux said yes, and all the flammables are stored in it.
- Ms. Morningstar asked if Ms. Wawro and Ms. Zimmerman had completed HazCom training; Ms. Simoneaux said yes they had.
- Mr. Harper said he would be interested to see the ATI lease agreement and if she is responsible for controlling access to the lab.
- Dr. Tang said he would provide informal oversight for safe practices, and Ms. Simoneaux could take over lab oversight. Dr. Tang said he would also help Ms. Wawro with the protocol to make all the appropriate corrections.

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how it would work if an issue came up between meetings; Ms. Myrick said it would be added to the agenda for the next regularly scheduled meeting. Ms. Morningstar said if there were no issues or protocols that need review or discussion, she would cancel the meeting in advance. Ms. Morningstar suggested the time they had been using, Wednesday at 3:00 p.m. The IBC agreed to meet the first Wednesday of each month at 3:00 p.m.

- The IBC proposed several changes to the IBC application, including a section where the PI lists their training and experience in the appropriate area, and in the chemical portion, which chemicals are being used for the protocol and which are simply stored in the lab.

5. Adjourn:

The meeting adjourned at 5:00 pm.



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IACUC convened at 3:00 pm on March 1, 2006 in the Conference Room 218 of the Office of Research Integrity & Compliance, 202 E. Border.

Attending Members:

Dr. Lorraine van Waasbergen	Assistant Professor, Biology	IBC Chair / rDNA Expert
Dr. Michael Roner	Assistant Professor, Biology	Vice-Chair / rDNA Expert / Animal Expert
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Mr. Stephen Harper		Non-Affiliated Member
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert
Ms. Viola Ohr	Water Quality Technician, City of Arlington	Non-Affiliated Member

Absent Members:

Dr. John Bacon	Professor, Biology	Plant Expert
Dr. Liping Tang	Associate Professor, Bioengineering	Animal Expert
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
Ms. Laura Simoneaux	Environmental Health & Safety	Biological Safety Specialist

1. Protocols for Review:

❖ **Ms. Debra Wawro: IBC Protocol #IBC06.006**

Staphylococcus aureus Binding

- Dr. van Waasbergen asked about her status as a student. Ms. Morningstar said she will check on Ms. Wawro's status, but she knows that there is some type of arrangement with the Arlington Technology Incubator (ATI). Dr. van Waasbergen said she wondered if Ms. Wawro would know about the procedures for disposal if she is only a student. Dr. Roner said that she needs approval for the use of the lab space if it is not hers. Dr. van Waasbergen said she may need to have a faculty sponsor who will supervise the work and be responsible for the protocol.
- Ms. Simoneaux mentioned that Ms. Wawro has completed radiation safety training.
- Ms. Ohr mentioned that in Table 5, it lists some chemicals as eye irritants, but eye protection is not listed under personal protective equipment. Dr. Roner pointed out that lab coats would be required for BSL-II work as well.
- Dr. van Waasbergen said that from the application, she is not sure what the PI is physically going to be doing. Ms. Morningstar said that further elaboration is needed on item #9, procedures.
- Mr. Sims said that he would be interested in the PI's timeline for some of the utilities she is requesting, such as the autoclave, since the PI said they are not purchased yet.
- Dr. Roner said that if she will be transporting hazardous waste across campus or between labs, she will need a plan for that. Ms. Simoneaux said she could assist Ms. Wawro with waste disposal issues.

The IBC tabled the protocol until further information could be obtained from the PI regarding procedures and employee/student status at UTA.

❖ **Dr. Michelle Badon: IBC Protocol #IBC06.007**

Microbiology Lab Coordinator

- Dr. Roner pointed out that on Table 2, the PI needs to change the status that is listed for the Personnel from "Faculty" to "Students."
- Dr. van Waasbergen asked if the PI will be required to update this as her students and personnel change. Dr. Roner said yes, she will need to update her protocol with an amendment.
- Dr. van Waasbergen asked if this application would be typical of a teaching lab protocol. Ms. Morningstar said yes, that she told the PI to generalize her procedures and group all of her chemicals together, so that it would be a general protocol that could carry over from semester to semester.

M/S/P *The IBC voted unanimously to approve the protocol pending the minor modification requested.*

2. Annual Report and Amendment for Review:

❖ **Dr. Lorraine van Waasbergen: IBC Protocol #IBC04.002**

Antibacterial Activity of Silver Compounds in Slow Release Polymers against Staphylococcus aureus

- Ms. Morningstar asked Dr. van Waasbergen if there have been any changes in her procedures from the last annual report. Dr. van Waasbergen said no, nothing has changed.

M/S/P *The IBC voted to approve the Annual Report. Dr. van Waasbergen abstained from voting.*

4. New Business / Announcements:

- Ms. Simoneaux provided an update on Dr. Carl Lovely's IBC protocol. She said that they have changed the location of their work, and the lab space they plan to use is a lab that uses radioactive material. She said all the personnel who will enter this lab will be required to complete radiation safety training and will require a radiation badge. Ms. Morningstar said their current protocol states the location of work is Science Hall 216, and there is not mention of radiation use. She said they will have to submit a revised protocol.

5. Adjourn:

The meeting adjourned at 4:00 pm.

MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IACUC convened at 3:00 pm on December 6, 2005 in the Conference Room 215 of the Office of Research Compliance, 202 E. Border.

Attending Members:

Dr. Lorraine van Waasbergen	Assistant Professor, Biology	rDNA Expert
Dr. Michael Roner	Assistant Professor, Biology	rDNA Expert / Animal Expert
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Ms. Viola Ohr	Water Quality Technician, City of Arlington	Non-Affiliated Member
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety

Absent Members:

Mr. Lee Hitchcock	Neighborhood Services, City of Arlington	Non-Affiliated Member
Ms. Pat Myrick	Director, ORIC	Human Gene Therapy Expert
Dr. John Bacon	Professor, Biology	Plant Expert
Dr. Liping Tang	Associate Professor, Bioengineering	Animal Expert

Guests:

Ms. Kirstin Morningstar	Office of Research Integrity & Compliance	Manager / IBC Coordinator
Ms. Laura Simoneaux	Environmental Health & Safety	Biological Safety Specialist

1. Review and Approval of Meeting Minutes:

- The minutes from the October 4, 2005 meeting were presented for review and discussion.

M/S/P *The Committee voted unanimously to approve the minutes.*

2. Protocols for Review:

❖ **Dr. Carl Lovely: IBC Protocol #IBC06.002**

Disk Diffusion Antibiotic Susceptibility Testing of Mycobacterium smegmatis

- Dr. van Waasbergen mentioned that Dr. Lovely's student was here last time, and it was determined that the organisms they are using are biosafety level 2, requiring IBC approval.
- Ms. Morningstar asked if EH&S had performed a lab inspection. Mr. Powell said no, but he believes it is Dr. Edward Bellion's lab in Chemistry. Ms. Morningstar said that final approval will have to wait until the lab inspection is complete.
- Mr. Sims asked if the lab requires card access. Mr. Powell said he believes the room is in fact equipped with card access.
- Mr. Powell said they would also have to follow up on the status of their hazard communication training.

M/S/P *The IBC voted unanimously to approve the protocol pending the completion of Hazard Communication training and an EH&S inspection of the laboratory.*

❖ **Dr. Jaroslaw Krzywinski: IBC Protocol #IBC06.003**

Transformation of E. coli

- Mr. Powell said that there are still issues with the mosquito lab and making sure it meets fire codes.

- Mr. Sims said Physical Plant met with them this morning for design work and his concern is for the HVAC system – it requires building a secondary chamber.
- Mr. Powell said in Part II of the protocol, for the laboratory safety plan, the wrong room number is listed.
- Dr. van Waasbergen said the microorganisms he is using are non-pathogenic.
- Mr. Powell asked if there will be any other personnel working on this project; Dr. van Waasbergen said no, just Dr. Krzywinski.

M/S/P *The IBC voted unanimously to approve the protocol following EH&S inspection of the finished laboratory space.*

❖ **Dr. Andre Pires da Silva: IBC Protocol #IBC06.004**

The Study of Regulatory Genes That Control Embryonic Development and Neurodegeneration

- Ms. Morningstar said that Dr. Pires da Silva combined two projects into one protocol, a tissue culture experiment and a recombinant DNA experiment.
- Mr. Powell said EH&S will do a lab inspection.
- Dr. Roner said that they will need bloodborne pathogen training and a biosafety hood for work with the heli cells.

Dr. Pires da Silva entered the meeting.

- Dr. Roner asked Dr. Pires da Silva where he will be doing the work; he said in the Chemistry department. Dr. van Waasbergen said he will need to list the other room number with the hood in it. Dr. Roner said he will not be able to bring the material between rooms.
- Dr. van Waasbergen asked if he will have access to an autoclave. Mr. Powell said that is something they will check on during lab inspection.
- Dr. van Waasbergen said that in the protocol, the strain of E. coli that is being used should be changed to Risk Group 1. Dr. Roner said that the neuroblasts should remain Risk Group II.
- Dr. Pires da Silva asked what happens if he wants to extract proteins. Dr. Roner said it should not be a problem, just write up a protocol.
- Ms. Morningstar said the protocol will be split into two parts, Part A being the rDNA work. She said Dr. Pires da Silva will need to submit an Amendment for Part B, the cell culture work, providing details on that experiment and including: location of work, completion of bloodborne pathogen training, and approval of laboratory space by EH&S.

Dr. Pires da Silva exited the meeting.

M/S/P *The IBC voted unanimously to approve Part A of the study (rDNA portion) pending the minor modifications requested.*

❖ **Dr. Elena de la Casa-Esperon: IBC Protocol #IBC06.005**

Study of the Chromatin Properties of the Om Region and of an X-Linked Gene Involved in the Control of Meiotic Recombination in Mouse

- Dr. van Waasbergen said this protocol has the same issue as Dr. Pires da Silva's – there is no cell culture facility. Dr. van Waasbergen said the strain of E. coli she is using is Risk Group I, not II.
- Dr. Roner said she did not list any cell lines for the cell culture work.

Dr. de la Casa-Esperon entered the meeting.

- Dr. van Waasbergen told Dr. de la Casa-Esperon that she can change the strain of E. coli that she is using to Risk Group 1. Dr. Roner said that since the cells she is using are mouse cells, not human, they are also Risk Group 1.

- Mr. Powell said it is not required for them to complete bloodborne pathogen training because there are no human cells involved, but they will still need to complete hazard communication training.
- Mr. Powell asked about the room listed on the laboratory safety plan portion of the protocol – will radiation be used in room 214? Dr. de la Casa-Esperon said there will not be, that is another lab.
- Dr. van Waasbergen suggested that Dr. de la Casa-Esperon be familiar with best practices with transport of materials between labs – she can either autoclave waste in the lab, or call EH&S for pick-up.
- Ms. Morningstar said the protocol will be split into two parts, Part A being the rDNA work. She said Dr. de la Casa-Esperon will need to submit an Amendment for Part B including details of the experiment and the location of the work.

Dr. de la Casa-Esperon exited the meeting.

M/S/P *The IBC voted unanimously to approve Part A of the study (rDNA portion) pending the minor modifications requested.*

3. Annual Report and Amendment for Review:

❖ **Dr. Michael Roner: IBC Protocol #IBC04.001**
HIV Antiviral Testing

- Dr. Roner said he is changing some personnel and adding a location. He said they would tend to want to restrict it to one room, and there are no plans to walk it across the hall. Dr. Roner said they want to move the work to room 333.
- Dr. van Waasbergen asked if he had a biosafety cabinet devoted to this; Dr. Roner said yes.
- Ms. Morningstar said the training of the new personnel will need to be verified; Mr. Powell said he would check.
- Dr. Roner said 333 already has all the proper signs. He said he does not want undergraduate students working on this - if they are infected with the virus there is no prophylaxis because they are not UTA employees covered by the Needlestick Policy. Mr. Powell said EH&S has set aside some money for this possibility, and workers compensation only recognizes the needlestick itself.
- Dr. van Waasbergen asked if the human risk group level III listed in Attachment C for HIV is correct. Dr. Roner said yes, HIV can infect humans, but it is hard to do. Mr. Powell said Dr. Roner's lab is looked at like a BSL-II Plus.

M/S/P *The IBC voted to approve the Annual Report. The IBC voted to approve the Amendment, pending verification of completion of training for new personnel. Dr. Roner abstained from both votes.*

4. New Business:

- Ms. Morningstar said that Annual Select Agent Surveys will be sent out next spring to faculty in Biology, Chemistry, and Bioengineering. She said the notification will also include information regarding what type of research requires review and approval from the IBC. Dr. van Waasbergen suggested that the notice be reviewed by the IBC before it goes out.

5. Announcements:

- Mr. Powell introduced Ms. Laura Simoneaux as the new biological safety specialist in EH&S.

6. Adjourn:

The meeting adjourned at 4:30 pm.



MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE

Members of the IBC convened at 3:00 pm on October 4, 2005 in the Conference Room 215 of the Office of Research Integrity and Compliance, 202 E. Border.

Attending Members:

Dr. Lorraine van Waasbergen	IBC Chair / Assistant Professor, Biology	rDNA Expert
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert
Mr. Lee Hitchcock	Neighborhood Services, City of Arlington	Non-Affiliated Member
Dr. John Bacon	Professor, Biology	Plant Expert
Ms. Viola Ohr	Water Utilities, City of Arlington	Non-Affiliated Member
Mr. Craig Powell	Director, Environmental Health & Safety	Biological Safety Officer/Lab Safety

Guests:

Ms. Kirstin Morningstar	Research Compliance Manager	IBC Coordinator
Ms. Pat Myrick	Office of Research Integrity & Compliance	Director

1. Protocols for Review:

❖ Dr. Cedric Feschotte: Protocol #IBC06.001

Transformation of E. coli

- Dr. van Waasbergen asked if anyone had any comments regarding the protocol. She said the procedures are typical cloning non-toxic materials using standard rDNA techniques.
- Dr. Bacon asked if Dr. Feschotte will be using the drug resistant form; Mr. Powell pointed out that the protocol does in fact state that he will be using the antibiotic resistant form.
- Mr. Powell said there are some issues with the use of radiation that are currently being resolved by the Radiation Safety Officer, however, it would not hold up the biological portion of the project in this protocol. Dr. Bacon asked what P33 is; Dr. van Waasbergen said that it is beta, but lower level and safer than P32. Mr. Hitchcock asked if the disposal procedures on page 5 meet required criteria; Mr. Powell said that the policy is that no radioactive material be disposed of down the drain except for the minimal amount that might occur while rinsing out glassware. EH&S picks up radioactive waste and stores it for decay and disposal.

M/S/P *The Committee voted unanimously to approve the protocol.*

2. New Business:

❖ Bacterial Testing, Mycobacterium smegmatis

- Ms. Lesley Schmid attended the meeting to address the Committee regarding her planned project. Ms. Schmid explained that they will be using Mycobacterium smegmatis in a non-virulent form for testing of antibiotic susceptibility. She said that the purpose is to see if they are drug targets for tuberculosis, and if anything is found to be positive, it will be sent outside the University. Ms. Schmid said that the experiments will take place in room 216 of the Life Science Building until the new building is finished, then they will move over to the new building.
- Ms. Schmid asked if mycobacterium smegmatis could be handled under Biosafety Level I procedures. Dr. van Waasbergen stated that it was her understanding that all mycobacteria are categorized in Biosafety Level II, except for some that are categorized in Biosafety Level III.



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- Dr. van Waasbergen asked what it typically grows in; Ms. Schmid said that it is listed as an opportunistic pathogen and is typically found in soil, although it can cause illness in immuno-compromised humans. Dr. van Waasbergen said that even though it is considered non-virulent, yet can still be infectious for immuno-compromised individuals, it will fall into Biosafety Level II.
- Ms. Morningstar stated that Biosafety Level I agents do not require IBC approval, but since mycobacterium smegmatis is categorized as Biosafety Level II according to *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), it will be required to go through the formal IBC review and approval process. Ms. Morningstar will forward the protocol application to Ms. Schmid.
- Mr. Powell mentioned that EH&S will perform an inspection of their laboratory space as part of the protocol review process.
- ❖ **Laboratory Biosafety Signs**
 - Mr. Sims asked if laboratories on campus are marked when they are Biosafety Level II labs. Ms. Morningstar said yes, there are currently only two BSL-II labs, and they are properly marked with biohazard signs.
- ❖ **Requirement for IBC approval**
 - Dr. van Waasbergen stated that she does not think all faculty know that they need approval for working with biohazardous materials and rDNA. Ms. Morningstar asked for any suggestions on how to get the word out. Ms. Myrick suggested putting a notice on the campus-wide listserv.
 - Dr. van Waasbergen mentioned that Biology's teaching labs do not have an IBC protocol, and some of the agents may require BSL-II procedures. Ms. Morningstar stated that there could be one protocol for the teaching lab that encompasses all the agents used or planned to be used. Dr. van Waasbergen stated that Michelle Badon would be the contact person for this; Ms. Morningstar said she would contact her for submission of a protocol.
- ❖ **IBC Policies and Procedures: Review and Update**
 - Ms. Morningstar stated that she had revised the Policy while completing UT System's Self-Assessment Tool. She distributed the revised Policy in advance of the meeting, and asked for any suggested changes to be forwarded to her.
- ❖ **IBC Self-Assessment Tool**
 - Ms. Myrick and Mr. Powell talked about the UT System Biosafety training they had attended and the IBC Self-Assessment Tool that was distributed at this training. UT System would like to receive comments back on the usability of the form by November 30. Ms. Morningstar stated that she had been working on the Self-Assessment, and once it is complete she can send it out to the Committee.

3. Announcements/News Update

- Mr. Powell stated that the issue of precursor chemicals is coming to light again; there will be a meeting about the issue next week to address the Memo of Understanding in order to ensure that these items are not getting to the general public.
- Ms. Morningstar stated that the IBC will now meet at least quarterly, but more often as needed in order to review annual reports, amendments, and new protocol applications, since the regulations do not address any other type of allowable review except for convened meetings of the IBC.

4. Adjourn - The meeting adjourned at 4:30 pm.



INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

Members of the IBC convened at 3:30 pm on October 26, 2004 in the Life Science Building.

Members Present:

Dr. Lorraine van Waasbergen	Assistant Professor, Biology	Chair
Dr. Michael Roner	Assistant Professor, Biology	Biocontainment Expert
Dr. Liping Tang	Associate Professor, Biomedical Engineering	Animal Containment Expert
Mr. Craig Powell	Director of Environmental Health & Safety	Laboratory Safety Expert
Mr. Bryan Sims	Associate Director, Physical Plant	Physical Containment Expert

Members Not Present:

Dr. John Bacon	Professor, Biology	Plant Containment Expert
Mr. Bob Byrd	City of Arlington	Non-Affiliated Member
Ms. Roni Crotty	City of Arlington	Non-Affiliated Member

Guests:

Ms. Kirstin Morningstar	Research Compliance Manager	IBC Coordinator
Ms. Stephanie Selby	Safety Specialist, EH&S	Laboratory Safety

1. Policy Review:

❖ Shipping and Receiving of Biohazardous Materials on Campus:

- ◆ Dr. Roner had made a formal request to Dr. van Waasbergen for the IBC to consider a policy change on the current procedures for shipping and receiving biohazardous materials on campus.
- ◆ Dr. Roner stated that he thinks the IBC should send a letter to Ron Elsenbaumer stating that biohazardous materials should be treated in the same manner as radioisotopes. Radioactive materials are currently shipped to the Environmental Health and Safety Office, where a safety specialist from EH&S delivers the package to the receiver.
- ◆ Mr. Powell stated that EH&S is here to provide support to the IBC, the IBC does not direct EH&S. He also feels that there are only a few PIs in which this applies to. He would still require PIs that receive packages to complete the annual shipping training. Mr. Powell suggested surveying the campus to see how many people ship and receive biohazardous materials, or fall under the IATA regulations. In the interim, EH&S will purchase and provide all the shipping and packing materials for individuals that need it. Mr. Powell stated that biohazardous materials are not the same as radioisotopes, and are not regulated in the same way. He said we should find out more about the University's need for this service before he can consider committing his budget and staff.
- ◆ Dr. van Waasbergen asked Dr. Roner what he feels the need is for this policy change, and if he has experienced any problems with the current system. Dr. Roner stated that he does not like the current system, as every other university seems to do it through their EH&S office – for instance, if you order something, it will have to be approved through their EH&S office before it is even shipped here.
- ◆ Mr. Powell suggested that other restrictions could be put in place to ensure compliance, such as restricting purchase of biohazardous materials on a pro card. Mr. Powell feels an even bigger issue for shipment of biohazardous materials is shipments between two institutions' laboratories, not necessarily shipments from vendors.
- ◆ Dr. Roner stated that he feels the regulations and shipping requirements are too complicated to expect individuals to ship items correctly each time, especially when the



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current training is only required annually, and the shipping regulations change frequently.

- ◆ Ms. Selby mentioned that EH&S is not currently equipped to accept packages of this nature if they had to be held, for instance, in a freezer. Dr. Roner stated that we have that problem anyway, in the Life Science Building – if the individual is not present, the package sits on a desk in the front office.
- ◆ Dr. van Waasbergen asked Dr. Roner what his particular need is for shipping. Dr. Roner stated that he currently does not have a need, he just feels it is dangerous the way the University currently does it, and no other institution handles it this way. Dr. Roner stated that under the current procedures, he could put anything in a box and ship it, and no one would know. Mr. Powell stated that UTA does plenty of other things that are not like other universities, and that we just need to figure out the scope of the problem before coming up with a plan.
- ◆ Mr. Sims asked how we could identify the need. Mr. Powell suggested sending out a survey to the users. Ms. Morningstar suggested sending it to Paul Paulus, College of Science Dean, for distribution to the appropriate users.
- ◆ Mr. Sims asked if this problem could affect anyone else besides the College of Science. Dr. van Waasbergen stated that biomedical engineering could also be affected. Mr. Powell mentioned that the Health Center would also be affected.
- ◆ Dr. van Waasbergen asked Mr. Powell to contact other universities with the same type of users and same size as UTA, to find out how they handle this situation.

Mr. Powell will draft some questions to be included on a survey, and send them to Ms. Morningstar for distribution to the campus.

❖ New IBC Forms – Annual Review Form and Amendment Form:

- ◆ Ms. Morningstar created two new forms – one for an annual review of an approved biosafety protocol, and another for an amendment to a biosafety protocol.
- ◆ Dr. van Waasbergen stated that she thinks the forms are good, and asked how the annual review process will be handled.
- ◆ Ms. Morningstar stated that annual reviews will be conducted at the one-year anniversary of the original approval of a biosafety protocol. She will notify the PI by sending an e-mail reminder with the annual review form attached. Then, the annual report and original protocol would be sent by e-mail for the Chair's review and approval, and the other IBC members would be copied for their review as well. If any member had any concerns or questions, it could be called to a full board meeting. This is how the IACUC currently handles annual reviews.

M/S/P

The Committee voted unanimously to approve the annual review form and the amendment form, and the review procedures for an annual review.

The meeting adjourned at 4:30 pm.

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Institutional Biosafety Committee (IBC) The University of Texas at Arlington

Minutes of Meeting: October 29th, 2003
Life Science Building, Room 210

Members Present:

Dr. Neal Smatresk	Chair	rDNA Technology Expert	Dean of Life Science
Dr. John Bacon	Voting Member	Plant Containment Expert	Biology
Dr. Michael Roner	Voting Member	Biological Safety Expert	Biology
Ms. Kirstin Morningstar	Non-Voting Member	Policy and Law	Research Compliance
Dr. Marianne Woods	Voting Member	Policy and Law	Asst. VP for Research
Mr. Robert Byrd	Voting Member	Non-affiliated	City of Arlington
Dr. Lorraine van Waasbergen	Voting Member	Biocontainment Expert	Biology

Members Absent:

Ms. Roni Crotty	Voting Member	Non-affiliated	City of Arlington
Dr. Liping Tang	Voting Member	Animal Containment Expert	Biomedical Engineering
Mr. Craig Powell	Voting Member	Laboratory Safety Expert	Director, EH&S
Mr. Bryan Sims	Voting Member	Physical Containment Expert	Assoc. Dir., Physical Plant

Guests:

Jennifer Bradley, Radiation & Biology Safety Specialist, Environmental Health & Safety
Brian Trotta, Research Compliance Specialist, Office of Research

The meeting convened at 2:30 p.m. with a quorum present.

1. An application for exemption was presented for Dr. Neal Smatresk and Dr. Jeremy Marshall involving bacteria samples taken from fish that will be collected in local streams, ponds, and lakes:
 - The IBC will review this research due to Dr. Smatresk's involvement. Dr. Smatresk usually reviews exemptions.
 - This work necessitates Biosafety Level 1 procedures. The work will be conducted in Life Science Building, room 242. Standard aseptic techniques will be used, and all materials will be autoclaved following the EH&S autoclave procedures outlined in the autoclave monitoring program. Work surfaces will be decontaminated before and after use. Room 242 remains locked and access is limited to the PIs and their graduate students.
 - The IBC unanimously approved this research; Dr. Smatresk abstained from voting.
2. Dr. Michael Roner's protocol application to use HIV was reviewed:
 - The work with HIV will be conducted following BSL-2 recommendations and procedures. Dr. Roner's lab has already been certified as BSL-2 by EH&S due to his existing work with vaccinia.
 - Dr. Roner stated that the level of safety has actually been increased, since every person in the laboratory will now also be completing EH&S's Bloodborne Pathogen training.
 - Dr. Roner is also in the process of receiving approval from the Institutional Review Board for the Protection of Human Subjects, since he will be using human cell lines in his work. Kirstin Morningstar stated that this will qualify for an IRB exemption, but she is waiting on Dr. Roner's and his students' completion of training.
 - The IBC unanimously approved the research protocol; Dr. Roner abstained from voting.
3. Dr. Woods stated that there should be a review of campus police emergency procedures, as evidenced during the fire on campus last weekend:

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- One police officer insisted on being present in Dr. Roner's vaccinia laboratory while Dr. Roner gathered supplies, even though Dr. Roner asked him to wait outside due to biosafety issues with the vaccinia. It is against IBC policy for non-trained, non-laboratory individuals to enter this vaccinia lab.
 - The police were inconsistent about letting people into the Animal Care Facility. Dr. Woods was not allowed in (even though she is on the emergency list for the facility), but the student workers were. But the student workers were not given ample time to fill out the log sheets and complete animal counts, which is required. The ACF has emergency power through a generator and the lights and electricity were working, so it was not a safety issue for the workers to be in the facility.
 - Dr. Smatresk will discuss the issue with Chief Hayes and Dana Dunn. As IACUC chair, Dr. Roner will also send an e-mail to Dana Dunn outlining these problems.
4. The IBC discussed the Autoclave Monitoring Program documents that Kirstin Morningstar presented at the last meeting:
 - There were no suggestions for any changes or edits. The IBC unanimously voted to approve the Autoclave Monitoring Program.
 5. The IBC discussed the IBC exemption forms:
 - The exemption form should come from the Office of Research as the full protocol form does. Ms. Morningstar will work to make this form available on the Office of Research website as an interactive pdf document.
 6. Dr. Smatresk asked the committee members to review the new IBC protocol forms:
 - The IBC will review the forms as if each person was filling them out for their own research. Are there any boxes that do not work, any formatting changes that are necessary, etc.?
 - Each member will compile their suggestions for edits and bring them to the next meeting.
 7. Ms. Morningstar requested that the next meeting have an agenda so the IBC members will be prepared to discuss each issue:
 - For the next scheduled meeting, IBC members will send agenda items to Ms. Morningstar to prepare a formal agenda.

The meeting adjourned at 3:25 p.m.

Institutional Biosafety Committee (IBC) The University of Texas at Arlington

Minutes of Meeting: October 7th, 2003
Life Science Building, Room 210

Members Present:

Dr. Neal Smatresk	Chair	rDNA Technology Expert	Dean of Life Science
Dr. John Bacon	Voting Member	Plant Containment Expert	Biology
Dr. Michael Roner	Voting Member	Biological Safety Expert	Biology
Ms. Kirstin Morningstar	Non-Voting Member	Policy and Law	Research Compliance
Dr. Marianne Woods	Voting Member	Policy and Law	Asst. VP for Research
Mr. Robert Byrd	Voting Member	Non-affiliated	City of Arlington
Mr. Bryan Sims	Voting Member	Physical Containment Expert	Assoc. Dir., Physical Plant
Dr. Lorraine van Waasbergen	Voting Member	Biocontainment Expert	Biology

Members Absent:

Ms. Roni Crotty	Voting Member	Non-affiliated	City of Arlington
Dr. Liping Tang	Voting Member	Animal Containment Expert	Biomedical Engineering
Mr. Craig Powell	Voting Member	Laboratory Safety Expert	Director, EH&S

Guests:

Dr. Kevin Nelson, Biomedical Engineering
Dr. Ronald Elsenbaumer, Associate VP for Research

The meeting convened at 4:00 p.m. with a quorum present.

Dr. Smatresk began the meeting by outlining what was going to be discussed:

- Autoclave Monitoring Program
- Biosafety Cabinet Inventory
- New Biosafety Lab Inspection Forms
- Survey for Select Agents
- Annual Recertification of IBC Protocols
- Dr. Roner's HIV Protocol Submission
- IBC Manual

1. Ms. Morningstar presented materials that were created for EH&S for the Autoclave Monitoring Program:

- "Safe and Effective Use of the Steam Autoclave" is an information sheet for autoclave users. The Board agreed to look over this document and present any suggestions to Craig Powell and Jennifer Bradley at the next meeting. Jennifer Bradley will be the new Radiation and Biology Safety Specialist for EH&S.
- "Autoclave Waste Treatment Record" is a log sheet for autoclave users to record all waste treated in the unit, as required by the Texas Commission on Environmental Quality. Dr. Roner and Dr. van Waasbergen stated that they have received an e-mail reminding them to use these log sheets.
- The Autoclave Inventory was also presented to the Board. Ms. Morningstar found a total of ten units before leaving her position at EH&S.
- Ms. Morningstar also provided autoclave users with a sheet of stickers stating: "Treated in Accordance with the provisions of 25 TAC § 1.136(a)." Ms. Morningstar stated that it is recommended to label an autoclaved biohazard bag with this sticker and then place in an opaque black trash bag before discarding in the regular trash. Mr. Byrd stated that sometimes, trash bags are torn open at the landfill, and the sticker, used in conjunction with a black trash bag, would help city employees identify what the waste is and determine that it has been treated.

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- ii. Dr. Roner has already received approval for another BSL II project, so his laboratory already meets the CDC/BMBL recommendations for a BSL II laboratory.
- 7. Dr. Smatresk reminded the Board that the IBC Manual, *Biohazard Recognition and Control: Guidelines for Handling Pathogenic Microorganisms and Disposing Biohazardous Waste*, is a working document. Copies will be distributed to new members. The Board should review the manual again for possible revisions and to ensure consistency with recent IBC decisions and policies.

The meeting adjourned at 5:30 PM.