



Institutional Biosafety Committee

March 27, 2006

Edward H. Hammond
Director
The Sunshine Project
P.O. Box 451987
Austin, TX 78704

RE: The University of Texas Health Center at Tyler Institutional Biosafety Committee (IBC)
Institutional Biosafety Meeting Minutes

Dear Mr. Hammond:

Per your request in your letter to Mr. Nick Huser on March 15, 2006 we are attaching the Minutes of all meetings of the University of Texas Health Center at Tyler Institutional Biosafety Committee (IBC) since 1 May 2003. Mr. Nick Huser has been replaced by Mr. Tony Hill, Director of Safety.

The University of Texas Health Center at Tyler IBC HAS / ~~HAS NOT~~ (please see below) implemented written policies for the identification, review, and oversight of research involving any of the seven categories of experience of concern identified by the National Academies of Science in its report *Biotechnology Research in an Age of Terrorism* (the "Fink Committee" report).

I am appending a copy of our new IBC application form that we will be using for reviewing IBC protocols. I would also like to note that in addition to our standard handbook of recombinant DNA (enclosed, currently being revised), we have developed an educational power point presentation describing the IBC policies and scope for UTHC-Tyler IBC members and Biomedical Researchers. I shall be happy to provide a copy of our IBC-training module, if you wish.

We trust that this meets with your approval.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Murty Madiraju".

Murty Madiraju, Ph.D.
Chairman, Institutional Biosafety Committee
Professor, Biochemistry

MM/pc
Attachment

**THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER
INSTITUTIONAL BIOSAFETY COMMITTEE
MARCH 15, 2006**

MEMBERS PRESENT: Dr. Murty Madiraju, Dr. Ming Cheh-Liu, Mr. Richard Ney, Dr. Malini Rajagopalan, Mr. Randall Tate, Mrs. Elaine Wells, Mr. Charles Wentworth

MEMBERS ABSENT: Dr. David Lakey

OTHERS PRESENT:

- I. **CALL TO ORDER:** The meeting was called to order at 12:03 p.m.
- II. **APPROVAL OF MINUTES:** The February 15, 2006 meeting of the Institutional Biosafety Committee was called to order at 12:03 p.m. by Dr. Murty Madiraju. The minutes were reviewed and approved. **Dr. Murty Madiraju is going to write a letter of explanation in the minutes.**

Elaine Wells made the **motion** to approve the minutes. Dr. Malini Rajagopalan **seconded**.

The minutes were approved with a correction made by Dr. Murty Madiraju which is the following:

Dr. Murty Madiraju was informed that the Infectious Organism Regulatory Research Committee (IORRC) was to be combined with the Institutional Biosafety Committee (IBC). The IORRC reports to the IBC. Dr. Madiraju will write a letter to Dr. Lakey stating that they should include the minutes of their meeting and write a few lines discussing the protocols. This is the only correction to the February 15, 2006 minutes.

- III. **OLD BUSINESS:**
There wasn't any old business.

IV. **NEW BUSINESS:**

PROTOCOL #118 – Structure and Function of SRP RNA - Christian Zwieb

Mrs. Elaine Wells made the **motion** to approve the protocol. Dr. Malini Rajagopalan **seconded**.

Approval with the following changes:

Page 3 A Host(s): Please specify strain number.

Page 4 #5. Significance: Line 2. SRp should be SRP.

APPROVED: 8

ABSTAIN: 0

OPPOSE: 0

APPROVAL WAS UNANIMOUS WITH CORRECTIONS.

Institutional Biosafety Committee

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PROTOCOL #119 – Structure and Function of tmRNA - Christian Zwieb

Dr. Ming Liu made the motion to approve the protocol. Dr. Malini Rajagopalan seconded.

Approval with the following changes:

Page 1: Project Title: tmRNP – should be tmRNA

Page 3. A. Host(s): Please specify strain number.

C. Gene(s) Line #1 "bacterial" should be "bacteria"

Page 4. #5: Significance: 3rd line tmRNP should be "tmRNA"

APPROVED: 8

ABSTAIN: 0

OPPOSE: 0

APPROVAL WAS UNANIMOUS WITH CORRECTIONS.

ADDENDUM 108b – Regulation of IFN-gamma in human tuberculosis – Buka Samten

Mr. Randy Tate made the motion to approve Addendum 108b. Malini Rajagopalan seconded.

Approval with the following changes:

Page 1: Scientific Objective (s) Please rewrite objective and check with the original Protocol #108.

APPROVED: 8

ABSTAIN: 0

OPPOSE: 0

APPROVAL WAS UNANIMOUS WITH CORRECTIONS.

- V. Dr. Murty Madiraju stated U.T. System wants to have better IBC practices. Dr. Steven Idell requested Dr. Madiraju to prepare a training post module for recombinant DNA to be used by all Researchers. It deals with chemical substances, environmental safety, recombinant DNA and radiation safety. The awareness of recombinant DNA is unknown and Dr. Madiraju will prepare a PowerPoint training presentation that everyone can use.

Every year we have to submit an IBC Roster Membership to NIH which Pat Casterline has done. NIH wanted a correction done because Mrs. Elaine Wells retired from UTHCT but remains a non-affiliate member and an updated CV had to be submitted. Everything is in order and we are awaiting an approval letter from NIH.

VI. ADJOURNMENT:

After conclusion of the March 15, 2006 meeting of the IBC, the meeting was adjourned by Dr. Murty Madiraju at 12:33 p.m.



Dr. Murty Madiraju
Chairman

Recorder: Pat Casterline
Institutional Biosafety Committee

**THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER
INSTITUTIONAL BIOSAFETY COMMITTEE
FEBRUARY 15, 2006
Protected under "list appropriate statutes"**

MEMBERS PRESENT: Dr. Ming Cheh-Liu, Dr. Murty Madiraju, Dr. Malini Rajagopalan, Mr. Randall Tate, Mr. Charles Wentworth, Mr. Tony Hill

MEMBERS ABSENT: Dr. David Lakey, Mr. Richard Ney, Mrs. Elaine Wells

OTHERS PRESENT:

- I. **CALL TO ORDER:** The meeting was called to order at 12:00 a.m.
- II. **APPROVAL OF MINUTES:** The February 15, 2005 meeting of the Institutional Biosafety Committee was called to order at 12:00 a.m. by Dr. Murty Madiraju. The minutes were reviewed and approved.

The minutes of November 16, 2006 meeting were reviewed. Mr. Charles Wentworth made the motion to approve the minutes. Dr. Ming Liu **seconded**.

APPROVED: 5 ABSTAIN: 0 OPPOSE: 0

APPROVAL WAS UNANIMOUS.

- III. **OLD BUSINESS:**
There wasn't any old business.

IV. **NEW BUSINESS:**

**PROTOCOL #117 –Regulation of apoptosis by anticancer and chemopreventive agents –
Rakesh Srivastava**

Dr. Ming Liu made the motion to approve the protocol. Dr. Malini Rajagopalan **seconded**.

Approval with the following changes:

Page 1: List protocols if any to be used.

Page 6: A. B. C. D. Fill out Potential Biohazards and Safety Considerations.

APPROVED: 5 ABSTAIN: 0 OPPOSE: 0

APPROVAL WAS UNANIMOUS WITH CORRECTIONS.

Institutional Biosafety Committee (IBC)

February 15, 2006

Page 2

- V. Dr. Murty Madiraju announced that Mrs. Elaine Wells had retired and a letter will be sent by Dr. Calhoun to appoint Mrs. Wells as an outside member for the IBC. Mr. Charles Wentworth announced that since Mrs. Wells would be an outside member he would like to retire from the IBC and the next meeting will be the last meeting he will be attending. A letter will be sent to NIH in March 2006 with the proper changes in the membership.

Dr. Murty Madiraju explained how the Institutional Biosafety Committee (IBC) and the Infectious Organism Research Review Committee (IORRC) correlates in relation to Recombinant DNA and infectious diseases and because of this correlation the IORRC would be a Subcommittee of the IBC and the minutes would be submitted here. The IBC purpose and goal is to address any IORRC concerns regarding Recombinant DNA and infectious diseases.

The Infectious Organism Research Review Committee (IORRC) minutes of the January 20, 2006 were reviewed by Dr. Murty Madiraju and explained to the IBC members. There was discussion regarding Applications for Training and the Protocol submitted by Dr. Pedro Flores. Dr. Madiraju stated that he would request a two-line summary of the Protocol be written in the minutes (along with the assigned number) to describe the protocol and its content.

There was a question regarding how the IBC would vote on the IORRC Protocols. It is suggested that the IORRC Minutes with adequate details be distributed to all IBC members prior to the IBC Meeting.

VI. **ADJOURNMENT:**

After conclusion of the February 15, 2006 meeting of the IBC, the meeting was adjourned by Dr. Murty Madiraju at 12:20 p.m.


Dr. Murty Madiraju
Chairman

Recorder: Pat Casterline
Institutional Biosafety Committee

**THE UNIVERSITY OF TEXAS HEALTH CENTER AT TYLER
INSTITUTIONAL BIOSAFETY COMMITTEE
SEPTEMBER 21, 2005
Protected under "list appropriate statutes"**

MEMBERS PRESENT: Dr. Murty Madiraju, Dr. Malini Rajagopalan, Mr. Nick Huser, Dr. Ming Cheh-Liu, Mr. Randall Tate,

MEMBERS ABSENT: Dr. David Lakey, Dr. Vijay Boggaram who was replaced by Dr. Malini Rajagopalan Mr. Charles Wentworth, Mr. Richard Ney

OTHERS PRESENT: Mrs. Shelley Turner, Compliance

I. CALL TO ORDER: The meeting was called to order at 11:45 a.m.

II. APPROVAL OF MINUTES: The September 21, 2005 meeting of the Institutional Biosafety Committee was called to order at 11:45 p.m. by Dr. Murty Madiraju. It was a brief meeting because Dr. Lakey could not attend because of medical emergencies and Mr. Nick Huser and Mrs. Shelley Turner of Compliance had an emergency meeting because of Hurricane Rita.

III. OLD BUSINESS:
There wasn't any old business.

IV. NEW BUSINESS:

There will be a special meeting held by Dr. Lakey:

Dr. Murty Madiraju stated that Dr. David Lakey attended the Southwest Regional Conference in San Antonio. Dr. Lakey has designated November 16, 2005 as a time to educate the IBC Committee about the conference. Per Shelley Turner, we will be submitting an IBC self-assessment tool to Dr. Idell, V.P. for Research.

Dr. Madiraju briefly explained that Dr. Su's protocol focuses on understanding the Thymus function in an effort to extend the function of aged thymus. This protocol was designated as BL2.

Votes were emailed from Dr. Malini Rajagopalan, Dr. Ming Cheh-Liu, Mr. Nick Huser and Mr. Randall Tate. Approval was unanimous. Attached are approval emails.

VII. ADJOURNMENT:

After conclusion of the September 21, 2005 meeting of the IBC, the meeting was adjourned by Dr. Murty Madiraju at 12:15 p.m.



Dr. Murty Madiraju
Chairman

Recorder: Pat Casterline
Institutional Biosafety Committee



Southwest Regional Conference for IBC Best Practices: Today and Tomorrow

August 18 - 19, 2005 San Antonio, Texas

Welcome Agenda Speakers Registration Travel List of Attendees

IBC Best Practices - Welcome

I am pleased to extend an invitation to come to San Antonio, Texas and join us in our scientific research outreach program. As you are aware, there has been increasing emphasis on complying with the National Institutes of Health (NIH) *Recombinant DNA Guidelines*, which promote safe and ethical research.

There are also important issues regarding the scope of Institutional Biosafety Committees and their relationship to other oversight mechanisms. We are very excited about bringing experts from the NIH Office of Biotechnology Activities to our conference to share their expectations on the roles and responsibilities of those committees and individuals who are involved in rDNA research. We hope you can come to San Antonio and bring your experience, knowledge, and questions in order to make this educational conference an enormous success.

Best Wishes,

Ken Shine, M.D.
Executive Vice Chancellor for Health Affairs
The University of Texas System

PRIM&R
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MEDICINE AND RESEARCH

For further information contact the Janet Cole
Last updated July 13, 2005

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
JULY 20, 2005**

MEMBERS PRESENT:

Dr. Murty Madiraju, Dr. Vijay Boggaram, Mr. Randall Tate and Mrs. Elaine Wells

Mr. Arthur Fokakis, Coordinator of Environmental Health and Safety was visiting in Mr. Nick Huser's absence.

MEMBERS ABSENT:

Dr. David Lakey

Dr. Ming-Cheh Liu

Mr. Richard Ney

Mr. Charles Wentworth

CALL TO ORDER:

The July 20, 2005 meeting of the Institutional Biosafety Committee was called to order at 12:00 p.m. by Dr. Murty Madiraju. The meeting was held in Conference Room #116 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of April 20, 2005 meeting were reviewed. Mrs Elaine Wells made the **motion** to approve the minutes. Dr. Vijay Boggaram **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

CHAIRMAN'S REPORT:

Dr. Murty Madiraju stated that lab inspections were done July 15, 2005 and all of the laboratories were done in wings A, B, C and D. CPIDC moved from the old labs to the new D Wing and had to submit addendums, which they did. There were no major problems and all laboratories were in compliance.

Institutional Biosafety Committee Minutes
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July 20, 2005

Dr. Madiraju also mentioned that in response to the Sunshine Project, UT. System's Dr. Ken Shine is organizing the Southwest Regional Conference for IBC Best Practices: Today and Tomorrow. The meeting will be held August 18 and 19, 2005. The office of Biotechnology of NIH will do lectures in San Antonio. Dr. Lakey, our Medical Officer, and Vice Chair will be attending this meeting.

OLD BUSINESS:

There wasn't any old business

NEW BUSINESS:

Protocol #110: Role of Syntaxin 4 and Munc 18c in Regulated Exocytosis of Weibel Palade bodies in endothelial cells - **Jian Fu**

Approval with the following changes:

Page 1. Change Proposed project period to 07/31/05 to 07/31/08.

Funding sources: Include Protocol numbers for Biohazardous Materials, Radiation Safety, Animal Research and Human Subjects Committees, if any, available.

Page 2: Do not check BL1.

Page 4: Section 5. Significance. Please elaborate.

Section 6. Part A. Please list chemicals.

Dr. Vijay Boggaram made the motion to approve the protocol. Elaine Wells seconded.

APPROVE: 4

ABSTAIN: 0

OPPOSE: 0

Approval was unanimous.

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July 20, 2005

Protocol 111 – Tyrosine Phosphatases and Endothelial Dysfunction –Hua Tang

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Mrs. Elaine Wells **seconded**.

Approval with the following changes:

Page 1: Proposed project period from 7/1/2005 to 6/30/2008.

Page 2: Do not check BL1.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

Protocol 112 – Regulation of interleukin-8 (IL-8) gene expression in lung cells – Vijay Boggaram

Dr. Vijay Boggaram stepped out of the room. Additional voting with Dr. Liu's vote.

Approval with the following changes: - Maybe the new form should be used.

Page 1: Funding states – “Planned” should be checked.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

Protocol 113 – Structural Mechanisms of Factor IXa Function –Pierre F. Neuenschwander

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Mrs. Elaine Wells **seconded**.

Approval with the following changes:

Page 1: Proposed project period from 4/1/2005 to 3/01/2008.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

Institutional Biosafety Committee Minutes
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July 20, 2005

Protocol 114 – Regulation of Blood Clotting and Fibrinolytic Proteases, and Their Role in Pathophysiology –L. Vijaya Mohan Rao

Mr. Randy Tate made the **motion** to approve the Protocol. Dr. Vijay Boggaram **seconded**.

Approval with the following changes:

Page 1: Proposed project period from 08/01/2005 to 07/31/2008.

Page 3: Section 3A, Second Paragraph. However all the hosts “will be” (was entered twice).

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

89a - Addendum –Mycobacterial genes that contribute to growth in macrophages – Peter Barnes

Dr. Boggaram made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

91a - Addendum – Induction and Assessment of cytotoxic T lymphocyte (CTL) response to Chlamydial and Mycobacterial pathogens – Benjamin Wizel

Dr. Boggaram made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

101a - Addendum – Characterization of mycobacterial peptide that is recognized by CD4+ and CD8+t-cells – Homayoun Shams

Dr. Boggaram made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

104b - Addendum – Activation of the lectin pathway of complement – Nenoo Rawal

Mr. Randy Tate made the **motion** to approve the Protocol. Dr. Vijay Boggaram **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

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July 20, 2005

107a - Addendum – Mycobacterial genes that contribute to the stress response – Susan Howard

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

108a - Addendum – Regulation of IFN-gamma in human tuberculosis – Buka Samten

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

109a - Addendum – The role of NK cells in human *M tuberculosis* in human tuberculosis –

Ramakrishna Vankayalapati

Mr. Randy Tate made the **motion** to approve the Protocol. Dr. Vijay Boggaram **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

93b - Addendum – Replication mechanisms and cell cycle control in mycobacteria –

Murty Madiraju

Dr. Murty Madiraju left the room while the Addendum was voted on. Additional voting with Dr. Liu's vote.

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

APPROVE: 4 ABSTAIN: 0 OPPOSE: 0

Approval was unanimous.

Institutional Biosafety Committee Minutes
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July 20, 2005

ADJOURNMENT

After conclusion of the July 20, 2005 meeting of the IBC, the meeting was adjourned by **Dr. Murty Madiraju**, at 12:40 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:



Murty Madiraju, Ph.D., Chairman, Institutional Biosafety Committee

7/28/05

Date

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
April 20, 2005**

MEMBERS PRESENT:

Dr. Murty Madiraju, Dr. Vijay Boggaram, Dr. David Lakey, Dr. Ming-Cheh Liu, Mr. Richard Nye, Mr. Nick Huser, Mr. Randall Tate, Mrs. Elaine Wells and Mr. Charles Wentworth

MEMBERS ABSENT:

None

CALL TO ORDER:

The April 20, 2005 meeting of the Institutional Biosafety Committee was called to order at 12:05 p.m. by Dr. Murty Madiraju. The meeting was held in Conference Room #116 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of February 16, 2005 meeting were reviewed. Mr. Nick Huser made the **motion** to approve the minutes. Mrs. Elaine Wells **seconded**.

APPROVE: 8 ABSTAIN: 0 OPPOSE: 0

CHAIRMAN'S REPORT:

Dr. Murty Madiraju stated that we obtained approval from NIH with an update of the registration for the Institutional Biosafety Committee (IBC). The Annual Report was sent to NIH March 1, 2005 and the approval letter was dated March 8, 2005.

Lab inspections will be conducted after June 10, 2005.

We have three (3) new faculty members that have been informed of the Recombinant DNA Protocol form. They also have been given the "Handbook for Investigators using Recombinant DNA in Research."

Institutional Biosafety Committee Minutes
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February 16, 2005

OLD BUSINESS:

There wasn't any old business

NEW BUSINESS:

Protocol #108: The role of NK cells in human *M. tuberculosis* infection - Ramakrishna Vankayalapati

Dr. Vijay Boggaram made the **motion** to approve the protocol. Elaine Wells **seconded**.

APPROVE: 8 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

Addendum 85b – Regulation of interleukin-8 (IL-8) gene expression in lung cells –
Vijay Boggaram

Mr. Nick Huser made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

APPROVE: 8 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous. ☐

Addendum 97b – Regulation of Lung Surfactant Protein Gene Expression - Vijay Boggaram

Mr. Wentworth made the **motion** to approve the Protocol. Dr. David Lakey **seconded**.

APPROVE: 8 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

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Institutional Biosafety Committee Minutes
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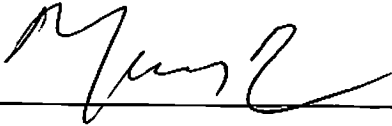
April 20, 2005

ADJOURNMENT

After conclusion of the April 20, 2005 meeting of the IBC, the meeting was adjourned by
Dr. Murty Madiraju, at 12:30 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:



4/21/05

Murty Madiraju, Ph.D., Chairman, Institutional Biosafety Committee

Date

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
November 17, 2004**

MEMBERS PRESENT:

Dr. Murty Madiraju, Mr. Richard Nye, Mr. Charles Parker, Mr. Randall Tate, Mrs. Elaine Wells and Mr. Charles Wentworth

MEMBERS ABSENT:

Dr. Vijay Boggaram
Dr. David Lakey
Dr. Ming-Cheh Liu

CALL TO ORDER:

The November 17, 2004 meeting of the Institutional Biosafety Committee was called to order at 12:15 p.m. by Dr. Murty Madiraju. The meeting was held in Conference Room #116 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of August 25, 2004 meeting were reviewed. Mr. Chuck Parker made the **motion** to approve the minutes. Mr. Charles Wentworth **seconded**.

APPROVE: 5

ABSTAIN: 0

OPPOSE: 0

CHAIRMAN'S REPORT:

Dr. Murty Madiraju discussed revisiting the labs on Monday, November 1, 2004 regarding IBC Inspections that were done August 9, 2004. Follow-ups were done and recommendations were made. There was one lab that was following up on one recommendation. All of the other laboratories were in compliance.

There were discussions regarding the Sunshine Project Report on IBC's.

The Handbook for Investigators using Recombinant DNA in Research was approved unanimously by the Committee. The Handbook will be bound and copies circulated to the entire Faculty.

Institutional Biosafety Committee Minutes
Page 2 of 3

November 17, 2004

OLD BUSINESS:

There wasn't any old business

NEW BUSINESS:

Protocol #104-a Addendum: Activation of the lectin pathway of complement– Neno Rawal (BSL2)

Elaine Wells made the **motion** to approve the protocol. Mr. Chuck Parker **seconded**.

Approval was made with appropriate changes:

The Protocol will be filled out on the addendum form.

APPROVE: 6 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

Protocol #105 – Control of Fibrin Turnover in Pleural Disease -Steven Idell, M.D., Ph.D. (BL2)

Charles Wentworth made the **motion** to approve the protocol. Richard Ney **seconded**.

Approval was made with the following appropriate changes:

On Page 1: Proposed project period from: Fill in the dates of the Proposed Period (spell out)
Protocols are approved only for three (3) years.

On Page 1: Funding Sources: Fill in the appropriate funding sources.

On Page 1: Designated area where experiments will take place: Fill in the designated area.

On Page 1: Changes required to upgrade the facility: Fill in appropriate changes.

On Page 1: Personnel involved in the project: Alexei Iakhiaev's name is misspelled.

On Page 1: Chemicals: "inorganic" should be "organic".

On Page 5: Radioactive Materials: "¹²⁵ I Na" (as written is incomplete).

Is it Iodine-¹²⁵-Radionuclide?

APPROVE: 6 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

Institutional Biosafety Committee Minutes
Page 3 of 3

November 17, 2004

Protocol #106 – Control of Fibrinolysis in Lung Disease – Sreerama Shetty

Elaine Wells made the **motion** to approve the Protocol. Mr. Chuck Parker **seconded**.

Approval with the following changes:

Page 1: Under Personnel involved in the project: Fill in all personnel involved in the project

Approval was unanimous.

APPROVE: 6 ABSTAIN: 0 OPPOSE: 0

ADJOURNMENT

After conclusion of the November 17, 2004 meeting of the IBC, the meeting was adjourned by **Dr. Murty Madiraju**, at 1:15 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:



Murty Madiraju, Ph.D., Chairman, Institutional Biosafety Committee

12/3/04

Date

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
August 25, 2004**

MEMBERS PRESENT:

Dr. Vijay Boggaram, Dr. Ming Cheh-Liu, Dr. Murty Madiraju, Mr. Richard Nye, Mr. Charles Parker, Mr. Randall Tate, and Mr. Charles Wentworth

MEMBERS ABSENT:

Dr. David Lakey
Mrs. Elaine Wells

CALL TO ORDER:

The August 25, 2004 meeting of the Institutional Biosafety Committee was called to order at 12:15p.m. by Dr. Murty Madiraju. The meeting was held in Conference Room #117 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of June 23, 2004 meeting were reviewed. Mr. Charles Wentworth made the **motion** to approve the minutes. Dr. Ming-Cheh Liu **seconded**.

APPROVE: 5

ABSTAIN: 1

OPPOSE: 0

CHAIRMAN'S REPORT:

Dr. Murty Madiraju discussed the comments regarding the annual Recombinant DNA work area inspections that were done on August 9, 2004. He read the comments made on each lab and the proposed plan of action which includes requesting the investigators to implement the IBC recommendations, if any. A copy of the letter will be sent to the Vice President for Research.

Revisions and corrections for The Handbook for Investigators using Recombinant DNA in Research were discussed in detail by the committee. Significant corrections will be made to the current Handbook and Dr. Murty Madiraju will compare the revised document with the NIH guidelines.

Institutional Biosafety Committee Minutes
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August 25, 2004

OLD BUSINESS:

There wasn't any old business

NEW BUSINESS:

Protocol #102 – Biochemistry of Sulfotransferase Enzymes – Ming-Cheh Liu

Dr. Boggaram made the **motion** to approve the protocol. Mr. Chuck Parker **seconded**.
Dr. Liu left the room.

APPROVE: 6 ABSTAIN: 1 OPPOSE: 0
Approval was unanimous.

Protocol #103 – Proteolysis of Factors V and VIII by the Factor VIIa-tissue Factor Complex
- Pierre F. Neuenschwander

Mr. Charles Wentworth made the **motion** to approve the protocol. Dr. Ming-Cheh Liu **seconded**.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0
Approval was unanimous.

Protocol #104 – Activation and regulation of the lectin pathway – Nenoo Rawal

Mr. Charles Wentworth made the **motion** to approve the Protocol. Mr. Randy Tate **seconded**.

Approval with the following changes: Page 1: Under Personnel involved in the project:
Take out “and others to be hired”.

Page 4:D: C is repeated in D. Spell out what genes (Name of genes).

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Institutional Biosafety Committee Minutes
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August 25, 2004

Protocol #85A- Addendum- Regulation of Interleukin-8 (IL-8) Gene Expression in Lung Cells -
Vijay Boggaram

Charles Wentworth made the **motion** to approve the Protocol. Dr. Ming-Cheh Liu **seconded**.

Approval was unanimous. Dr. Boggaram left the room.

Approved: 6 Abstain: 1 Opposed: 0

Protocol #93A- Addendum- Replication mechanisms and cell cycle control in mycobacteria -
Murty Madiraju

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Dr. Ming-Cheh Liu **seconded**.

Approval was unanimous.

Dr. Murty Madiraju left the room.

APPROVE: 6 ABSTAIN: 1 OPPOSE: 0

Protocol#97A- Addendum – Regulation of Lung Surfactant Protein Gene Expression
Vijay Boggaram

Mr. Chuck Parker made the **motion** to approve the Protocol . Mr. Randy Tate **seconded**.

Approval was unanimous. Dr. Boggaram left the room.

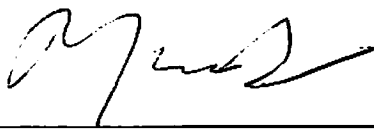
APPROVE: 6 ABSTAIN: 1 OPPOSE: 0

ADJOURNMENT

After conclusion of the August 25, 2004 meeting of the IBC, the meeting was adjourned by **Dr. Murty Madiraju**, at 1:40 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:

 9/7/04

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
June 23, 2004**

MEMBERS PRESENT:

Dr. David Lakey; Dr. Ming-Cheh Liu, Dr. Murty Madiraju, Mr. Richard E. Nye, Mr. Charles Parker, Mr. Randall Tate, and Mrs. Elaine Wells

MEMBERS ABSENT:

Dr. Vijay Boggaram
Mr. Charles Wentworth

CALL TO ORDER:

The June 23, 2004 meeting of the Institutional Biosafety Committee was called to order at 12:00 p.m. by Dr. Murty Madiraju. The meeting was held in Conference Room #116 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of January 21, 2004 meeting were reviewed. Chuck Parker made the **motion** to approve the minutes. Dr. Liu **seconded**.

Approval was unanimous.

APPROVE: 7

ABSTAIN: 0

OPPOSE: 0

CHAIRMAN'S REPORT:

Dr. Murty Madiraju opened the meeting by explaining that we called this special meeting because of the following reason:

Recently, we received a letter from NIH –Office of Biotechnology Activities (OBA) saying that they did not approve our Membership Roster. Dr. Don Killebrew from U.T. Tyler is one of our IBC members and OBA felt that it leads to a biased membership and suggested that we submit a member not associated with UT System. Consequently, we had to replace Dr. Killebrew with Mr. Richard E. Nye.

Mr. Nye asked questions regarding the IBC and its roles. Both Drs. Madiraju and Lakey gave an overview of the IBC's purpose and commitment.

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June 23, 2004

The Inspection Checklist was handed out and discussed. The Annual Recombinant DNA Inspection of all labs is proposed to be conducted next month. The corrections on the Handbook for Investigators using Recombinant DNA in Research were handed out for the committee to correct.

OLD BUSINESS:

There wasn't any old business.

NEW BUSINESS:

Protocol #101 – Characterization of a mycobacterial peptide that is recognized by CD4+
And CD8+ T-cells - **Homayoun Shams**

Mrs. Elaine Wells made the **motion** to approve the Protocol. Dr. Lakey **seconded**.

Approval was unanimous.

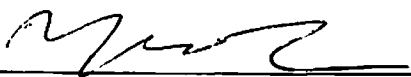
APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

ADJOURNMENT

After conclusion of the June 23, 2004 meeting of the IBC, the meeting was adjourned by **Dr. Murty Madiraju** at 12:35 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:



Murty Madiraju, Ph.D., Chairman, Institutional Biosafety Committee

7/28/04

Date

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
January 21, 2004**

MEMBERS PRESENT:

Dr. Vijay Boggaram, Dr. Ming-Cheh Liu, Mr. Charles Parker, Mr. Randall Tate, and Mr. Charles Wentworth

MEMBERS ABSENT:

Dr. Don Killebrew

Mrs. Elaine Wells

Dr. Murty Madiraju (Dr. Boggaram Chaired the meeting

Dr. David Lakey arrived at 12:30 p.m.

CALL TO ORDER:

The January 21, 2004 meeting of the Institutional Biosafety Committee was called to order at 12:00 p.m. by Dr. Vijay Boggaram. The meeting was held in Conference Room #116 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of September 17, 2003 meeting were reviewed. Dr. Liu made the **motion** to approve the minutes. Charles Wentworth **seconded**.

APPROVE: 5

ABSTAIN: 0

OPPOSE: 0

CHAIRMAN'S REPORT:

(Since Dr. Murty Madiraju was absent, the Chairman's Report was not discussed).

OLD BUSINESS:

There wasn't any old business.

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September 17, 2003

NEW BUSINESS:

The IBC Recombinant DNA work area inspection checklist was handed out and comments/changes were made. Any additional comments and suggestions should be sent to Dr. Murty Madiraju.

On Inspection:

2. IBC-safety manuals, protocols and addenda (if any); are they readily accessible to all employees.
3. b. should read "are the above reagents located close to the work area"?
4. a. is there a designated recombinant DNA waste container
4. d: Is the recombinant DNA waste stored properly?

Protocol #100 – Coagulation and Fibrinolytic Proteases and Signaling – Usha Pendurthi

Dr. Boggaram made the motion to approve the Protocol. Mr. Chuck Parker seconded.

Approval with the following changes:

Proposed Project period from November ____ 2003 to November ____ 2006. The day of the month should be filled in.

On Section 6-A Chemicals: Please submit a list of chemicals and how they will be disposed of to Mr. Chuck Parker, Safety Department.

APPROVE: 5

ABSTAIN: 0

OPPOSE: 0

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ADJOURNMENT

After conclusion of the January 21, 2004 meeting of the IBC, the meeting was adjourned by **Dr. Vijay Boggaram** at 12:45 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:



1/29/04

Murty Madiraju, Ph.D., Chairman, Institutional Biosafety Committee

Date

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
September 17, 2003**

MEMBERS PRESENT:

Dr. David Lakey, Dr. Vijay Boggaram, Dr. Murty Madiraju, Mr. Charles Parker, Mr. Randall Tate, Mrs. Elaine Wells, and Mr. Charles Wentworth

MEMBERS ABSENT:

Dr. Don Killebrew
Dr. Ming Cheh-Liu

CALL TO ORDER:

The September 17, 2003 meeting of the Institutional Biosafety Committee was called to order at 12:10 p.m. by Dr. Murty Madiraju. The meeting was held in Conference Room #117 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of July 16, 2003 meeting were reviewed. Chuck Parker made the motion to approve the minutes. Charles Wentworth **seconded**.

APPROVE: 7

ABSTAIN: 0

OPPOSE: 0

CHAIRMAN'S REPORT:

1. Since it was decided in our last meeting that the PI's would be notified a few months before expiration of their recombinant DNA research Protocols, we have received many protocols for review. We will continue to remind the PI's in advance regarding their protocols.
2. We have a new BSL-3 facility beside two BSL-3 trailers. The new facility is designed for animals infected with bacteria. Since our (Murty Madiraju and Malini Rajagopalan) current work requires that we have access to a BSL-3 facility, it was decided by the administration that we could use the new facility until more permanent arrangements are made.

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3. We also have a new Infectious Disease Safety Committee and the new committee members are Dr. David Lakey, (Chairperson), Dr. Mark Atkinson, Dr. Ronald Dodson, Becky Wilson, Richard Wallace, and myself. This Committee replaces the old BSL-3 Committee. The work in my lab deals with the strains of avirulent and virulent *M.tuberculosis*. It was approved by the new BSL-3 Committee that our current work with avirulent strains of *M.tuberculosis* can be carried out in our Labs A5 and A6.
4. Per our internal audit report, we need to prepare a check list for recombinant DNA work area inspection and post inspection follow-up procedures, if any.

OLD BUSINESS:

Dr. Murty Madiraju stated that when we conducted the recombinant DNA work areas inspections, we found that the Fermenter room, which is a shared facility, requires a Biohazardous trash can, paper towels, soak-absorbent materials, bleach, ethanol bottles, etc. We would like to know who would be responsible for providing these supplies so that we can maintain safe work areas. Dr. Zwieb is in charge of this facility.

NEW BUSINESS:

Protocol #91 – Induction and Assessment of cytotoxic T lymphocyte (CTL) responses to Chlamydial and Mycobacterial pathogens – Benjamin Wizel

Dr. Vijay Boggaram made the **motion** to approve the Protocol.. Mr. Randy Tate **seconded**. Approval was unanimous.

Approval with the following changes: Check BL3. Clarify Page 2: Known pathogens are toxic. Do this under BL2 conditions instead of BL1.

APPROVE: 7

ABSTAIN: 0

OPPOSE: 0

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September 17, 2003

Protocol #92 – Cell division regulators in mycobacteria – Malini Rajagopalan.

Mr. Charles Wentworth made the **motion** to approve the Protocol. Mrs. Elaine Wells **seconded**.
Approval was unanimous.

Approval with the following changes: BSL3 – with clarification;

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Protocol #93 – Replication mechanisms and cell cycle control in mycobacteria - Murty Madiraju

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Mr. Chuck Parker **seconded**.
Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Protocol #94- Structure and Function of SRP RNA- Christian Zwieb

Dr. David Lakey made the **motion** to approve the Protocol. Mr. Charles Wentworth **seconded**.

Approval with the following changes: SRP RNA needs to be spelled out. Take out check marks and put NA on page 1. Remove small boxes on page 2 under BL1.

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Protocol#95- BER coregulation with replication and energy metabolism – Zafer Hatahet

Dr. David Lake made the **motion** to approve the Protocol . Mr. Charles Wentworth **seconded**.

Approval with the following changes: Funding needs to be checked on the first page. Change date on front page to 8/31/06.

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

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September 17, 2003

Protocol #96 – Activation of the Alternative Pathway of Complement – Michael Pangburn

Dr. Vijay Boggaram made the **motion** to approve the Protocol. Mrs. Elaine Wells **seconded**.
Approval with the following changes: First page Personnel involved. How many Wang's are there?

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Protocol #97 – Regulation of Lung Surfactant Protein Gene Expression – Vijay Boggaram

Mrs. Elaine Wells made the **motion** to approve the Protocol. Mr. Chuck Parker **seconded**.

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Protocol #98 – Function of α -2-Macroglobulin in Inflammation – Anna K. Kurdowska.

Dr. David Lakey made the **motion** to approve the Protocol. Dr. Vijay Boggaram **seconded**.

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Protocol #99 – SP-A Receptor Mediated Mechanisms of Phagocytosis – Zissis Chroneos.

Dr. David Lakey made the **motion** to approve the Protocol. Mr. Charles Wentworth **seconded**.

Approval with the following changes: Page 1 "Biochemistry" is misspelled. Check BL` and BL2. Do a general spell check.

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0


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ADJOURNMENT

September 17, 2003

After conclusion of the September 17, 2003 meeting of the IBC, the meeting was adjourned by **Dr. Murty Madiraju**, at 1:30 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:



Murty Madiraju, Ph.D., Chairman, Institutional Biosafety Committee

1/5/04

Date

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
July 16, 2003**

MEMBERS PRESENT:

Dr. David Lakey, Dr. Ming Cheh-Liu, Dr. Murty Madiraju, Mr. Charles Parker, Mr. Randall Tate, Mrs. Elaine Wells, and Mr. Charles Wentworth

MEMBERS ABSENT:

Dr. Don Killebrew
Dr. Vijay Boggaram

CALL TO ORDER:

The July 16, 2003 meeting of the Institutional Biosafety Committee was called to order at 12:00 p.m. by Dr. Murty Madiraju. The meeting was held in Conference Room #116 in the Biomedical Research Building.

APPROVAL OF MINUTES:

The minutes of July 17, 2002 meeting were reviewed. Mrs. Elaine Wells made the **motion** to approve the minutes. Dr. Liu **seconded**.

APPROVE: 7

ABSTAIN: 0

OPPOSE: 0

CHAIRMAN'S REPORT:

Dr. Murty Madiraju stated that the IBC meeting will be held when there is a Protocol to review for approval. A minimum of one meeting per year will be held to review and discuss recombinant DNA work area inspections and any other relevant issues.

Dr. Murty Madiraju reported that on July 9, 2003, Dr. Boggaram, Chuck Parker, Randy Tate, Pat Casterline and himself conducted the Recombinant DNA lab inspections. The general conclusions were the following:

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July 17, 2003

Report of lab inspections by Randy Tate and Vijay Boggaram

Lab A4 (Pangburn)

1. The biohazardous waste material container lacked a lid.

Lab A2 (Chroneos)

1. The biohazardous waste material container lacked a lid.

Lab A1 (Tang)

1. Biohazardous waste was found stored in a cardboard box (with appropriate liner_ without a lid.

Biotech Student Lab (Hedrick)

(There was nobody in the lab)

1. Bleach or any other suitable disinfecting agent was not found on the bench tops although many containers of bleach were found underneath the sink in the main lab.
2. A suitable container for the biohazardous material could not be found.

Lab ? (Liu)

1. An unautoclaved biohazardous material bag was found discarded in the medical waste container.
2. A separate container needed for the biohazardous waste material could not be found.

Report of lab inspections Labs C

Dr. Rao and Pendurthi: Everything is okay.

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Dr. Zwieb:

Fermenter Room requires the following:

1. A biohazard trash can.
2. Sock (absorbent material to contain fermenter spills, if any, in a timely manner).

OLD BUSINESS:

There wasn't any old business

NEW BUSINESS:

As per the new regulations, we will be submitting annual inspections and quarterly reports pertinent to lab safety to Dr. Atkinson.

Dr. Madiraju suggested that PI's be issued a letter 6 months before their protocol expires stating that they need to renew their protocol, then 3 months later issuing another reminder letter.

Protocol #62-a Addendum – Biological Processing of Oxidative DNA lesions –Zafer Hatahet
Dr. Lakey made the motion that Dr. Hatahet submit a new Protocol. Mr. Wentworth seconded.
“Biomedical” was misspelled on page 1. Please resubmit a new protocol. Resubmit with temporary approval.

APPROVE: 0

ABSTAIN: 0

OPPOSE: 0

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Protocol #66-a Addendum – Induction and Assessment of Cytotoxic T lymphocyte (CTL) responses to Mycobacterial and Chlamydial Pathogens - Benjamin Wizel.

Dr. Lakey made the **motion** that Dr. Wizel submit a new Protocol. Mr. wentworth **seconded**. **Project Title was not completed. Resubmit with temporary approval.**

APPROVE: 0 ABSTAIN: 0 OPPOSE: 0

Protocol #69b Addendum – Activation of the Alternative Pathway of Complement- Michael Pangburn

Dr. Lakey made the **motion** to approve the Protocol. Dr. Liu **seconded**. **Protocol will expire next month. Send a reminder letter.**

Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

Protocol #73a- Regulation of Lung Surfactant Protein Gene Expression - Vijay Boggaram

Dr. Lakey made the **motion** to approve the Protocol. Elaine Wells **seconded**. **Send a reminder letter in 6 months.** Approval was unanimous.

APPROVE: 7 ABSTAIN: 0 OPPOSE: 0

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Protocol#79-a Addendum – Control of fibrinolysis in Lung Disease – Sreerama Shetty

Dr. Lakey made the **motion** to approve the Protocol with the following changes. Randy Tate **seconded**.

1. **Page 3: A: Host “Resistance is misspelled.**
2. **Remove Brad Low from “Personnel involved in the project.”**

APPROVE: 7

ABSTAIN: 0

OPPOSE: 0

**Protocol #88 – Cytokines Production by *Pseudomonas aeruginosa*: Role of MAP Kinases–
Ali Azghani**

Mr. Wentworth made the **motion** to approve the Protocol. Randy Tate **seconded**. Approval was unanimous.

APPROVE: 7

ABSTAIN: 0

OPPOSE: 0

Protocol #89 – Mycobacterial genes that contribute to growth in macrophages– Peter Barnes

Mr. Wentworth made the **motion** to approve the Protocol with the following changes. Dr. Liu **seconded**.

1. **Clarify what Biohazardous materials were to be used.**

APPROVE: 0

ABSTAIN: 0

OPPOSE: 0

**Protocol #90 – Cell division in *Mycobacterium tuberculosis* and FtsZ protein -
– Malini Rajagopalan.**

Randy Tate made the **motion** to approve the Protocol. Mr. Wentworth **seconded**. Approval was unanimous.

APPROVE: 7

ABSTAIN: 0

OPPOSE: 0

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July 17, 2003

ADJOURNMENT

After conclusion of the July 16, 2003 meeting of the IBC, the meeting was adjourned by **Dr. Lakey, M.D.**, at 1:13 p.m.

Minutes respectfully submitted by Pat Casterline.

Chairman's Approval:



8/4/03

Murty Madiraju, Ph.D., Chairman, Institutional Biosafety Committee

Date

Protocol #	
Date Received:	
Date Approved:	
Biosafety Level	

The University of Texas Health Center at Tyler

Institutional Biosafety Committee

REQUEST FOR APPROVAL OF THE USE OF RECOMBINANT DNA

1. General

Principal Investigator: _____

Department: _____

Phone: _____

Project Title: _____

Proposed project period from _____ to _____

Funding sources: *Federal* ☐ *State* ☐ *Private* ☐ *Department* ☐ *Other* ☐

Designated area where experiments will take place: _____

Changes required to upgrade the facility: _____

Personnel involved in the project:

--

Note: The Principal Investigator assumes complete responsibility for the competence of the people who will be handling the recombinant DNA in the project.

Committees which will review or have reviewed this application:
(Provide protocol number only if approved)

Biohazardous Materials Committee
Radiation Safety Committee
Animal Research Committee
Human Subjects Committee

Protocol # _____
Protocol # _____
Protocol # _____
Protocol # _____

2. Biosafety levels of containment (type "x" on applicable lines)

☐ BL1

Work involving agents of no known or of minimal potential hazard to laboratory personnel and the environment. Special containment equipment is not required or generally used. The following applies to agents assigned to BL1:

- ☐ Access to the laboratory is limited.
- ☐ Disinfectants are available for decontaminating work surfaces once a day and after a spill.
- ☐ All contaminated wastes are decontaminated before disposal. Material is transported in a closed, durable, leak-proof container if leaving the laboratory.
- ☐ Eating, drinking, and applying cosmetics are not permitted in the work area. Food may only be stored in cabinets or refrigerators designated and used for this purpose, and must be located outside the work area.
- ☐ Equipment for mechanical pipetting is available; mouth pipetting is prohibited.
- ☐ All procedures are performed carefully to minimize the creation of aerosols.
- ☐ Pests (insect, rodents ...) are controlled.

☐ BL1-LS

For large-scale (> 10 liters) work. In addition to BL1 practices, BL1-LS requires:

- ☐ A closed vessel for propagation and growth of cultures.
- ☐ Organisms shall not be removed from the closed system unless inactivated.
- ☐ Sample collection is done such that the release of aerosols is minimized.

☐ BL2

Work involving agents of moderate potential hazard to personnel and the environment. BL2 requires, in addition to BL1 and BL1-LS practices, that:

- ☐ The laboratory personnel have specific training in handling pathogenic agents.
- ☐ Certain procedures in which infectious aerosols are created are conducted in biological safety cabinets (Class I or II) or other physical containment equipment.

☐ BL3

Work with indigenous or exotic agents where the potential for infection by aerosols is real and the disease may have serious or lethal consequences. Autoinoculation and ingestion also represent primary hazards to personnel working with these agents. BL3 requires, in addition to BL2 practices, that:

- ☐ Access is controlled
- ☐ Partial containment equipment is used for manipulation of infectious material.
- ☐ Special laboratory clothing is used.

☐ BL4

Work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. BL4 requires, in addition to BL3 practices, that:

- ☐ Class III biological safety cabinets or partial containment equipment in combination with full-body, air-supplied, positive-pressure personnel suit are used for all procedures and activities.
- ☐ Entrance through change room where street clothing is removed and laboratory clothing is put on; shower on exit.
- ☐ All wastes are decontaminated on exit from the facility.

Note: Levels BL2-LS and BL3-LS and BL-4 are currently not supported.

3. Hosts, vectors, and plasmids used

A. Host(s):

Provide species name(s), strain(s), drug resistance marker(s) and information about the pathogenicity of the host(s).

B. Vector(s):

Provide the name(s) and relevant components(s) of the vector(s). Include replication requirements (bacteria, yeast, higher eukaryotes), type and origin of the promoter (s), viral components(s), and drug resistance marker(s) (constitutive and inducible) and pathogenicity of the vector(s).

C. Gene(s):

Provide name(s), function(s), pathogenicity, and relevant characteristics of the gene(s) used.

D. Deliberate attempts will be made to express the following gene(s):

E. What are the culture volume(s) to be used:

F. Risks to man:

4. Scientific objective(s)

State the scientific objectives of this protocol.

5. Significance

Briefly justify the importance of the objectives in **lay terms**, relating it to a known medical or scientific problem. **Note:** This section must be repeated verbatim on all addenda to this application and it will be the standard by which the appropriateness of all addenda will be judged.

6. Potential biohazards and Safety considerations.**A. Chemicals****B. Radioactive materials****C. Animals**

Briefly address the following issues: Will recombinant DNA (introduction of viral vectors, creation of transgenic animals, knockouts, DNA vaccinations, etc) or infectious agents be introduced into animals? If so, give details of genes/ vectors/ infectious agents / recipient species/ mouse strain as well as methods of injection). Describe the expected phenotype of the animal (e.g. immunodeficient, early disease onset/ resistance, etc.). Also address whether animals show signs of clinical disease, and whether the agent(s) be shed/ excreted by the infected animals. Provide animal project number approved for this project.

D. Human Subjects**7. Assurance by the PI**

As Principal Investigator, I understand that I am ultimately responsible for the use of recombinant DNA. I agree to abide by the policies of the Institutional Biosafety Committee and all federal, state, and institutional policies, laws, and guidelines concerning the use of recombinant DNA. I have fully disclosed to the Committee all relevant information and agree to notify and seek approval from the Institutional Biosafety Committee prior to implementation of any procedural changes in the project regarding the use of recombinant DNA.

Each investigator must designate whether, in their judgment, the proposed recombinant DNA work fit into an area of concerns (Experiments of Concern) as listed below.

That my proposal:

	YES	NO
1. Would demonstrate how to render a vaccine ineffective	<input type="checkbox"/>	<input type="checkbox"/>
2. Would confer resistance to therapeutically useful antibiotics or antiviral agents	<input type="checkbox"/>	<input type="checkbox"/>
3. Would enhance the virulence of a pathogen or render a non-pathogen virulent	<input type="checkbox"/>	<input type="checkbox"/>
4. Would increase transmissibility of a pathogen	<input type="checkbox"/>	<input type="checkbox"/>
5. Would alter the host range of a pathogen	<input type="checkbox"/>	<input type="checkbox"/>
6. Would enable the evasion of diagnostic/ detection modalities	<input type="checkbox"/>	<input type="checkbox"/>
7. Would enable the weaponization of a biological agent or toxin	<input type="checkbox"/>	<input type="checkbox"/>

These seven categories of concern have been identified by the "Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology", National Academies of Sciences, Chaired by Dr. Gerald R. Fink.

Please note, if answer to any of the above questions is "YES", then please explain. The IBC will review, weigh potential benefits versus potential danger. If need be, the proposals will be referred to NIH- Recombinant DNA Advisory committee for approval or denial of permission to proceed with the proposed experiment.

Signature

Date