



NEBRASKA'S HEALTH SCIENCE CENTER

INSTITUTIONAL BIOSAFETY COMMITTEE

April 24, 2006

Mr. Edward Hammond
Director
The Sunshine Project
PO Box 41987
Austin, TX 78704

RE: Minutes of IBC Meetings since May 2003

Dear Mr. Hammond

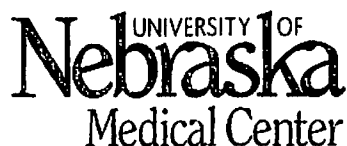
In response to your letter dated March 15, 2006, the University of Nebraska Medical Center Institutional Biosafety Committee has attached copies of all meeting minutes beginning with October 2004 to the present. We understand your request for minutes beginning with 1 May 2003; however the IBC conducted most of its reviews electronically prior to October 15, 2004, and in any case, does not have minutes of the earlier meetings as they do not exist.

Sincerely

A handwritten signature in blue ink that reads "Dave Crouse".

Dave Crouse, PhD
Associate Vice Chancellor
Academic Affairs/Graduate Studies

cc: Jay Noren, Executive Vice President and Provost
Richard Wood, Vice President and General Counsel
Ernest Prentice, PhD
Oksana Lockridge, PhD
Pete Iwen, PhD



INSTITUTIONAL BIOSAFETY COMMITTEE

NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
February 10, 2006**

MEMBERS PRESENT:

Paul Fay, Ralph

ALTERNATE NON-VOTING PRESENT

ADMINISTRATIVE STAFF PRESENT: Gail

[] e opened the meeting at 3:03pm

A. Review and Acceptance of IBC Minutes

The January 13, 2006 minutes were accepted as written.

B. Information, Education and Policy Items

Information

The IBC was notified that [] nn will be retiring from the University on March 31, 2006. All Board members present wished her well and informed her that she will be missed. Sally was thanked for her dedication to the ORA Office.

Discussion was held regarding the email notices that are sent out to investigators when the protocols are determined to be exempt from IBC review. [] will work with [] to make the suggested changes and send to the members for review and further input.

[] in asked the Board about whether maintaining the status on ABL2 research is needed following 72 hours. The Comparative Medicine policy has been to quarantine animals for 72 hours following administration of an infectious agent. When the r deficient adenovirus or other Recombinant DNA agent is contained in cells that have been cultured for 72 hours before administration of the cells to animals, must the animals still be quarantined? The IBC suggested that this precaution still be followed.

Education

The following educational item was distributed and key points discussed: News from the NIH Office of Biotechnology Activities. January 18, 2006.

Policy

The IBC voted (07 in favor, 0 against, 1 abstention) to approve the Shipping and Receiving of Category A High Consequence Pathogens [SOP#UNMC-IBC30] policy.

C. Incident and Event Reports

No report

D. Special Notification and/or Review

No Reports.

IBC MINUTES
February 10, 2006
Page 2

E. IBC Change in Protocol

IBC#: 04-10-044-BL2

PI: , MD, PhD

TITLE: Regulation in HIV-1 Associated Dementia

Outcome: A change in protocol was brought to the board for full board review. The IBC voted (7 in favor, 0 against, 1 abstention) to conditionally approve the request for change pending verification of 1) all personnel being added to the research who work in the cell sorting facility are trained; and 2) inspection of the cell sorting facility has been performed by n. An email detailing the specific points will be sent and reflected in Addendum I of the minutes. All IBC members listed as present voted.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 03-04-010-BL1

PI: PhD

TITLE: Triplet Repeat Instability in Cultured Human Cells

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to designate the status of this study as exempt per Section III-F and Appendix C of the NIH Guidelines. An email detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-02-006-BL1

PI: ova, PhD

TITLE: 1) Mutagenesis mediated by lesion bypass DNA polymerases. 2) Role of DNA polymerases in chromosome stability control. 3) Mechanisms of mutagenesis mediated by translesion synthesis DNA polymerase.

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to conditionally approve the continuing review pending receipt of a list of all genes being expressed and types of vectors being used for the host organisms. An email detailing the specific points will be sent and reflected in Addendum I of the minutes. All IBC members listed as present voted.

IBC #: 04-05-024-ABL1

PI: R PhD

TITLE: Assessment of cell signaling

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to conditionally approve the continuing review pending verification of training for all personnel. A letter detailing the specific points will be sent and reflected in Addendum I of the minutes. All IBC members listed as present voted.

IBC MINUTES
February 10, 2006
Page 3

IBC #: 05-03-007-BL1

PI: ' PhD

TITLE: DNA Polymerases in Lagging and Leading Strands Replication

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to designate the status of this study as exempt per Section III-F and Appendix C of the NIH Guidelines. An email detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 03-04-011-ABL2

PI: PhD

TITLE: Function of the PVN in heart failure: role of NO and NMDA, Normalization of enhanced NMDA receptor-mediated sympathetic outflow in heart failure: effect of nNOS gene transfection into the PVN.

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to conditionally approve the continuing review pending verification of the animal laboratory being utilized for this research. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-03-008-ABL2

PI: 3, PhD

TITLE: Genetic Vaccines for Cancer

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to conditionally approve the continuing review pending verification of the alternative vectors being used; 2) training; and 3) personnel involvement. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-03-010-ABL2

PI: An PhD

TITLE: Role of Astroglial Activation in Chronic Inflammation Neurodegenerative Diseases

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to conditionally approve the continuing review pending verification of the laboratory being used. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-03-013-BL2

PI: 7 in, MD

TITLE: Third-Generation Lentiviral Expression Vectors for cDNA and siRNA

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-04 015-ABL2

PI: 2000000, PhD

TITLE: Regulation of Antigen Presentation

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

IBC MINUTES
February 10, 2006
Page 4

IBC #: 05-03-008-BL3-SA

PI: MD

TITLE: Protein Profile Analysis of Select Agents and Relevant Comparators

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members reviewed a BL1 application for initial review and/or 5-year rewrite to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

PI:

TITLE: APOBEC4, novel member of DNA/RNA deaminases family

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) that this research is exempt from IBC review per the NIH Guidelines Section III-F-6, Appendix C-II (Escherichia coli K-12 Host Vector Systems), and Appendix C-III (Saccharomyces Host Vector Systems). No further action will be required by the IBC. An email detailing this determination will be sent and reflected in Addendum 1 to the minutes. All IBC members listed as present voted.

I. IBC Initial Review and/or 5-year Rewrites of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

None

There being no further business, the meeting adjourned at 3:45 p. m.

Respectfully Submitted,



O
Chair, IBC

OL/gdk

xc: Ru PhD
s, MD
ID
st, PhD



INSTITUTIONAL BIOSAFETY COMMITTEE

NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
January 13, 2006**

MEMBERS PRESENT:

ALTERNATE NON-VOTING PRESENT: 5

ADMINISTRATIVE STAFF PRESENT:

opened the meeting at 3:07pm

A. Review and Acceptance of IBC Minutes

The December 09, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

Pe further information or review on the tularemia incident.

distributed the toxic agent list to and review.

informed the IBC that the ABL3 lab in the DRC will be up and running in a few weeks.

will send the electronic version of original submissions to reviewers for any of the BL1 studies that are up for continuing review. This will help the IBC in determining whether or not a study is exempt or should remain a BL1.

Education

The following educational item was distributed and key points discussed: Everything You Want to Know or Not Know About the Select Agent Rule. Power Point Presentation; Carol Whetstone, PhD; South Central Association for Clinical Microbiology Audio-conference, December 6, 2005.

Policy

The IBC voted (08 in favor, 0 against, 1 abstention) to conditionally approve the Shipping and Receiving of Category A High Consequence Pathogens [SOP#UNMC-IBC30] policy. This policy will be revised and brought back for further review at the February 2006 IBC meeting.

C. Incident and Event Reports

No report

D. Special Notification and/or Review

No Reports.

E. IBC Change in Protocol

No Reports.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 02-03-009-BL1

PI: _____, PhD

TITLE: 1. Lysophosphatidic acid and its receptors in health and disease. 2. Lysophosphatidic acid and smoking-related airway disease. 3. Lysophosphatidic acid as a mediator in asthma. 4. Regulation of lung cell EGF receptor expression by GPCRs.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to complete this study and designate as exempt. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 03-03-003-BL1

PI: _____, PhD

TITLE: Endogenous Ligands of Galectin-3 in Cancer Cells

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to complete this study and designate as exempt. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-04-016-BL1

PI: _____ PhD

TITLE: Nebraska Center for Cellular Signaling: The role of desmosomes in oral squamous cell carcinoma

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the continuing review pending verification of all personnel involved in the research as being trained. A letter detailing the specific points will be sent and reflected in Addendum I of the minutes. All IBC members listed as present voted.

IBC #: 04-05-026-BL1

PI: _____, PhD

TITLE: 1) Regulation of growth factors and embryogenesis. 2) Inactivation of the k-FGF-4 gene in embryonic stem cells

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

IBC #: 05-01-002-BL1

PI: _____, PhD

TITLE: Regulation of Human Prostatic Acid Phosphatase Signaling in Androgen-Refractory Prostate Cancer Signaling in Human Prostate Neuroendocrine Cells

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to complete this study and designate as exempt. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 03-03-005-BL2

PI: Y PhD

TITLE: 1) Role of ERK1/2 Signaling in BRCA1-Mediated G2/M Arrest. 2) ERK/2 signaling in BRCA1-mediated DNA damage response.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the continuing review pending verification of signature of the principal investigator. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-03-011-BL2

PI: 's, PhD

TITLE: 1) Regulation of lung cell EGF receptors by GPCRs; 2) G protein-coupled receptor regulation of EGF receptors; 3) G protein-coupled receptor modulation of lung cell EGF receptor expression and function; 4) Opposite regulation of epidermal growth factor receptors by G protein coupled receptors in airway smooth muscle cells.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-03-014-ABL2

PI: irp, PhD

TITLE: Transduction of stem cell and related cell populations with marker, selection and gene silencing vectors followed by assay of in vitro and in vivo effects.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-12-055-BL3

PI: chs, MD

TITLE: United States national Domestic Preparedness Program

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

3 DHS

IBC #: 05-02-006-ABL2

PI: MD, PhD

TITLE: Macrophages, neuronal K channels and HIV-1 associated dementia

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the continuing review as submitted. All IBC members listed as present voted.

IBC MINUTES
January 13, 2006
Page 4

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members reviewed a BL1 application for initial review and/or 5-year rewrite to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 05-12-025-BL1

PI:

TITLE: Use of a murine retroviral vector in studies of antigen presentation

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the study as a BL1 protocol. A letter notifying the PI will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exception: 1, _____ was absent from the room at the time of the vote.

I. IBC Initial Review and/or 5-year Rewrites of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC # 05-12-023-ABL2

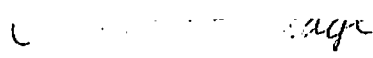
PI:

TITLE: 1) Blood-brain barrier tight junctions during HIV-1 dementia. 2) Improving the CNS delivery of anti-retroviral compounds. 3) Effect of alcohol on HIV-1 immune responses & BBB damage. 4) Interactions of block copolymers in blood brain barrier. 5) PPAR mediated neuroprotection against HIV-1 and alcohol CNS injury.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the ABL2 study pending modification to the protocol. An email detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

There being no further business, _____ adjourned the meeting at 4:07 p. m.

Respectfully Submitted,


_____, PhD

Chair, IBC

OL/gdk

xc: D _____ PhD
_____ MD
_____ PhD
_____ st, PhD

NEBRASKA'S HEALTH SCIENCE CENTER

MEMBERS PRESENT: [illegible] Chair, [illegible] Vice-Chair, [illegible]
[illegible], [illegible], [illegible], [illegible], [illegible]

ADMINISTRATIVE STAFF PRESENT - 10:00 AM

The November 11, 2005 minutes were accepted as written.

Per Data base no further information on the tularemia incident.

uld like a statement added to the continuing review certification of principal investigator statement to comply with the Select Agent Rule. The IBC agreed to incorporate additional wording in the existing language.

... discussed at length the responsibility of inspections and monitoring of the 12 autoclave core facilities. The IBC decided to have Pete Iwen and the IBC Administrative staff discuss this further in order to facilitate the most appropriate actions.

The following educational item was distributed and key points discussed: 1. Select Agent Information. Office of Extramural Research – National Institutes of Health; December 1, 2005.

No policies reviewed.

No report

IBC MINUTES

December 09, 2005 Meeting

Page 2

D. Special Notification and/or Review

Review a continuing review which involves training only

IBC # 05-01-004-BL2-SA

PI:

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve retaining the BL2-SA training access protocol as submitted. All IBC members listed as present voted with the following exceptions 1) Ralph Hauke was absent from the room at the time of the vote; and 2) _____ was excused from the meeting and did not participate in the discussion or vote.

E. IBC Change in Protocol

No Reports.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 02-01-002-ABL1

PI:

TITLE: Effect of a novel protein kinase on AD pathogenesis

Outcome: The IBC voted (11 in favor, 0 against, 1 abstention) to conditionally approve the ABL1 continuing review pending verification of animal labs. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 02-02-008-BL1

PI:

TITLE: 1. Mechanisms of desensitization of adrenergic receptors. 2. Caveolar localization, function and regulation of alpha-1 adrenergic receptors. 3. Upregulation of G-protein mutated alpha-1 adrenergic receptors by protection from inherent instability

Outcome: The IBC voted (11 in favor, 0 against, 1 abstention) to approve closing out this study and changing the status to exempt. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-01-003-ABL1

PI:

TITLE: Cadherins in oral squamous cell carcinoma

Outcome: The IBC voted (11 in favor, 0 against, 1 abstention) to conditionally approve the ABL1 continuing review pending verification of training certification. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 05-01-003-BL1

PI:

TITLE: Mechanisms of Bax Activation

Outcome: The IBC voted (11 in favor, 0 against, 1 abstention) to approve closing out this study and changing the status to exempt. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC MINUTES

December 09, 2005 Meeting

Page 3

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 01-12-016-BL2

PI:

TITLE: ica phase variation in *Staphylococcus epidermidis*

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote; and 2) [redacted] excused from the meeting and did not participate in the discussion or vote.

IBC #: 02-12-033-RI 3-SA

PI: [redacted]

TITLE: Molecular characterization and pathogenesis of *Francisella tularensis*

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to conditionally approve the BL3-SA continuing review pending verification of labs being utilized. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC #: 02-12-034-RI.2

PI:

TITLE: The role of immune responses in alcoholic liver disease

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. The database will be changed to reflect ABL2. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC #: 02-12-035-RI 3-SA

PI:

TITLE: Immune responses to *Coxiella burnetii*

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to conditionally approve the BL3-SA continuing review pending verification of labs being utilized. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: [redacted] was absent from the room at the time of the vote.

IBC #: 03-01-001-BL3-SA

PI:

TITLE: Population genomics of *Francisella tularensis*

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the BL3-SA continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote; and 2, [redacted] was excused from the meeting and did not participate in the discussion or vote.

IBC MINUTES
December 09, 2005 Meeting
Page 4

IBC #: 03-03-009-ABL2

PI:

TITLE: Test system for HIV-1 vaccine evaluation

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to conditionally approve the ABL2 continuing review pending clarification of labs being utilized, training certification, and the title. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC #: 04-03-012-ABL2

PI: [redacted]

TITLE: Human/pig hybrid model of hepatitis C virus for new vaccines

Outcome: The IBC voted (11 in favor, 0 against, 1 abstention) to conditionally approve the ABL2 continuing review pending clarification of which laboratory facilities in Oakland, Nebraska will be utilized. A letter detailing the specific points will be sent and reflected in Addendum I to the minutes. The All IBC members listed as present voted.

IBC #: 05-01-011-BL2

PI: [redacted]

TITLE: 1) Molecular dissection of IGF2R growth suppressor activity. 2) Insulin-like growth factor binding protein-6 and prostate cancer

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members reviewed a BL1 application for initial review and/or 5-year rewrite to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

PI: [redacted]

TITLE: Characterization of DNA elements with gene-regulatory function in vivo

Outcome: The IBC voted (11 in favor, 0 against, 1 abstention) to approve the study as an ABL1 protocol. A letter notifying the PI that the protocol is not exempt will be sent and reflected in Addendum I to the minutes. An IBC number was assigned following the meeting: 05-12-024-ABL1. All IBC members listed as present voted.

I. IBC Initial Review and/or 5-year Rewrites of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 00-11-014-BL2

PI: [redacted]

TITLE: Centers for Disease Control and Prevention. West Nile Virus Surveillance.

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to approve the BL2 5-year rewrite as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC MINUTES
December 09, 2005 Meeting
Page 5

There being no further business

the meeting adjourned at 3:55 p. m.

Respectfully Submitted,

[Signature]
Chair, IBC

Chair, IBC

OL/gdk

xc:

PhD

MD

MD

ist, PhD



INSTITUTIONAL BIOSAFETY COMMITTEE

NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
November 11, 2005**

MEMBERS PRESENT:

W. ...

ALTERNATE NON-VOTING PRESENT.

ADMINISTRATIVE STAFF PRESENT:

... ge opened the meeting at 3:03pm

A. Review and Acceptance of IBC Minutes

The October 14, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

chs stated No further information on the tularemia incident.

No information on ORA office procedures was discussed.

Pete Iwen sent an email notifying the IBC regarding the Select Agent 1918 Influenza Rule. The Board did not feel there were concerns at this time for UNMC.

Education

The following educational item was distributed and key points discussed: Welcome to a new standard in strategic knowledge exchange and network: Dream or Nightmare? Facilitate Advisory Boards; 10/26/2005; Pages 1 – 6.

Policy

No policies reviewed.

C. Incident and Event Reports

4/26/05 Incident Update: Results of the follow-up chest x-ray were received by the IBC. The x-ray was normal. A final report will be sent to the investigator which will complete the review on this incident.

D. Special Notification and/or Review

No Reports

E. IBC Change in Protocol

No Reports.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 02-12-036-BL1

PI:

TITLE: BCL3 Transcriptional Response to Immunological "Danger"

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-01-002-BL1

PI:

TITLE: 1) Mechanisms of gap junction regulation. 2) Mechanisms of control of cell growth by gap junctions. 3) Role of connexin-32 in tumor suppression

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 03-12-030-ABL2

PI: F hD

TITLE: 1) Inhibition of lymphangiogenesis and immune augmentation using Adv-VEGF-CsiRNA vectors. 2) Potentially novel antitumor synergy between anti-lymphangiogenesis and immune augmentation strategies. Molecular regulation of human melanoma metastasis.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the ABL2 continuing review pending lab inspections scheduled for November 18, 2005. All IBC members listed as present voted.

IBC #: 04-05-018-BL2

PI:

TITLE: Blood-brain barrier physiology and HIV dementia

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the BL2 continuing review pending training certification on all investigators. All IBC members listed as present voted.

IBC #: 04-05-019-BL2

PI: F

TITLE: Molecular mechanisms of HIV-mediated encephalopathy

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 as submitted. All IBC members listed as present voted.

IBC#: 04-05-020-BL2

PI:

TITLE: Neural Immunity in HIV Dementia

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 as submitted. All IBC members listed as present voted.

IBC#: 04-05-021-BL2

PI:

TITLE: Training Program in Neurovirology

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 as submitted. All IBC members listed as present voted.

IBC #: 04-05-028-BL2

PI:

TITLE: Immunopathogenesis of HIV neurological disorders. Project 2: Monocyte immunity and HIV-1 induced dementia

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 as submitted. All IBC members listed as present voted.

IBC #: 04-05-030-BL2

PI:

TITLE: Molecular Mechanisms of HIV Neuropathogenesis

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the ABL2 continuing review pending training certification on all investigators. All IBC members listed as present voted.

IBC #: 04-12-053-BL2

PI:

TITLE: 1) Adenoviral transfection of endocytic recycling regulatory proteins. 2) Role of recycling for integrin mediated function

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 as submitted. All IBC members listed as present voted.

IBC #: 04-12-05

PI:

TITLE: Signaling mechanisms in the ovary

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 as submitted. All IBC members listed as present voted.

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

No Submissions

I. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

No Submissions

There being no further business

adjourned the meeting at 3:20 p. m.

Respectfully Submitted,

C. J. ... je, PhD

Chair, IBC

OL/gdk

xc:

PhD

ies, MD

3, PhD

'st, PhD



NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
October 14, 2005**

MEMBERS PRESENT:

ALTERNATE NON-VOTING PRESENT:

ADMINISTRATIVE STAFF PRESENT:

opened the meeting at 3:03pm

A. Review and Acceptance of IBC Minutes

The September 9, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

stated that the tularemia incident continues to be an ongoing investigation. No further information was provided.

Update on ORA office procedures

1. The IBC discussed whether or not exempt applications that are reviewed should be entered into the database. It was decided by the Committee not to enter protocols into the database. The ORA staff will maintain an exempt hard copy file to retain the protocols.
2. Discussion on whether or not the nurse coordinator who takes care of vaccine patients in 's protocol should be listed on the IBC protocol. The Committee determined that the training must be completed if this individual is listed on the protocol. The previous nurse coordinator had completed the training and was involved with administration of the vaccine. Patients and family members are given safety instruction sheets.
3. questioned the numbering system for 5 year rewrites. After a lengthy discussion, the IBC decided that all protocols 2000 or greater would maintain their current number in order to avoid confusion and facilitate links to grants and other regulatory approvals. This also facilitates maintenance of ORA documentation for each project.
4. The Clorox Bleach now being used in laboratories meets FDA standards as a disinfectant.

A Quarterly Compliance Report – July 1 through September 30, 2005 was distributed to the IBC. This report is sent on behalf of the IBC to the UNMC Compliance Committee, chaired by J.L.

Education

The following educational item was distributed and key points discussed: 1) Playing It Safe With Research Risk. The Chronicle of Higher Education; Karen M. Markin; August 12, 2005; Pages 1–5.

Policy

No policies reviewed.

C. Incident and Event Reports

9/6/05 Incident Update: will continue to follow this incident. Department of Employee Health workers will receive refresher training for UNMC/The Nebraska Medical Center current policy for evaluating contract workers in the event of injury or exposure to a hazard while working on our campus.

4/26/05 Incident Update: will request the results of the follow-up chest x-ray. The person involved in this incident is moving to a research lab in Texas.

D. Special Notification and/or Review

No Reports

E. IBC Change in Protocol

No Reports.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 02-11-026-BL1

PI: .

TITLE: Biochemical Study of Apoptosis Mediated by Calcium

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC #: 03-08-017-BL1

PI: PhD

TITLE: 1) Role of endocytic recycling regulatory proteins and their impact on cholesterol trafficking. 2) Deciphering the roles of endocytic recycling regulatory proteins and their chronology of action. 3) Integrating molecular mechanisms of endocytic recycling. 4) Impact of endocytic recycling on EGF receptor function. 5) Role of recycling for integrin-mediated function.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-12-051-ABL1

PI: ID

TITLE: Gene and protein therapy for poisoning by organophosphorus agents

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted with the following exceptions 1; was excused from the meeting and did not participate in the discussion or vote.

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 00-11-011-BL2

PI:)

TITLE: 1) Genetic Pathways in Mammary Gland Development and Cancer. 2) Jak2 deficiency and memo cancer progression.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 – ABL1 continuing review as submitted. All IBC members listed as present voted.

IBC #: 02-11-029-BL3-SA

PI:

TITLE: Center for Disease Control and Prevention – Laboratory Response Network Level-C Diagnostic Testing for Variola Virus; Electron Microscopy and "Real-time" PCR

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL3-SA continuing review as submitted. All IBC members listed as present voted.

IBC #: 02-11-031-BL3-SA

PI:

TITLE: Molecular Genetic Analysis of Francisella Tularensis

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the BL3-SA continuing review as submitted. All IBC members listed as present voted with the following exceptions 1; was excused from the meeting and did not participate in the discussion or vote.

IBC#: 02-11-032-BL2

PI:

TITLE: Adenovirus p53 infected DC vaccine for breast cancer

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. All IBC members listed as present voted.

IBC #: 03-11-028-ABL2

PI: ID

TITLE: Chemoreflex Function in Heart Failure

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the ABL2 continuing review as submitted. All IBC members listed as present voted.

IBC #: 03-11-029-BL2

PI:

TITLE: A phase II randomized, double blind, controlled study to evaluate the safety and efficacy of prostatic acid phosphatase (PAP) in combination with GM-CSF in patients with androgen-independent adenocarcinoma of the prostate

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the BL2 continuing review pending training certification on all investigators. All IBC members listed as present voted.

IBC #: 04-11-047-BL2

PI:

TITLE: Armed Forces Institute of Pathology Critical Reagent Genomic Repository Program

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the BL2 continuing review pending training certification on all investigators. All IBC members listed as present voted.

IBC #: 04-12-052-BL3

PI:

TITLE: Development and validation of diagnostic procedures for the identification of micro-organisms including mycobacteria

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the BL3 continuing review as submitted. All IBC members listed as present voted with the following exception 1) [Name] was excused from the meeting and did not participate in the discussion or vote.

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

PI:

TITLE: Identification and Characterization of Genes Associated with Photoreceptor Development

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) that this research falls under exempt and is not under the purview of the IBC Board. A letter detailing these specific points will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

I. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 05-09-021-BL2

PI:

TITLE: 1) Genetic Pathways in Mammary Gland Development and Cancer. 2) Jak2 Deficiency and Mammary Cancer Progression

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 5-year re-write as written. It was also noted that the new number will be withdrawn and the study will retain its current IBC # 00-11-011-BL2. A letter of approval under the initial IBC # will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 05-09-022-BL3

PI: [REDACTED]

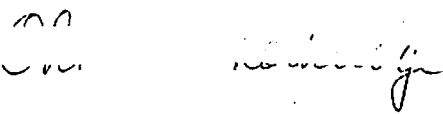
TITLE: Armed Forces Institute of Pathology Critical Reagent Genomic Repository Program, Risk Group 3 Agents

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to conditionally approve the BL3 pending receipt and acceptance of the following: (1) a letter of clarification and revisions to the IBC Protocol in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exception 1) [REDACTED] was excused from the meeting and did not participate in the discussion or vote.

There being no further business,

adjourned the meeting at 3:58 p. m.

Respectfully Submitted,



Ernest D. [REDACTED]
Chair, IBC

OL/gdk

xc: [REDACTED] use, PhD
[REDACTED] MD
Ernest D. [REDACTED], PhD
[REDACTED] st, PhD



NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
September 9, 2005**

INSTITUTIONAL BIOSAFETY COMMITTEE

MEMBERS PRESENT:

31

ALTERNATE NON-VOTING PRESENT:

ADMINISTRATIVE STAFF PRESENT: None

opened the meeting at 3:00pm

A. Review and Acceptance of IBC Minutes

The August 12, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

1 stated that the tularemia incident continues to be an ongoing investigation. No further information was provided.

No updated ORA office procedures were discussed.

cussed in detail samples of exempt research. It was suggested that samples of research within the university be put together in order to help not only the IBC committee but also investigators to determine what represents exempt research versus research that would be considered BL1 and need review by the IBC committee. It was suggested that these samples be put onto the IBC website. provided examples and will provide examples to . The updated document will be reviewed at a future IBC meeting.

Education

The following educational items were distributed and key points discussed 1) National Science Advisory Board for Biosecurity: Purpose, Structure, and Operations. NSABB Inaugural Meeting, June 30 – July 1, 2005; 2) National Science Advisory Board for Biosecurity: Balancing Biosecurity and Scientific Progress: The Need for Culture of Responsibility. Anthony S. Fauci, MD; NSABB Inaugural Meeting, June 30 – July 1, 2005; and 3) National Science Advisory Board for Biosecurity. Dual-use Results and Scientific Journals. Philip Campbell, Editor-in-Chief, Nature; NSABB Inaugural Meeting, June 30 – July 1, 2005.

Policy

The IBC voted (8 in favor, 0 against, 1 abstention) to approve with minor revisions the Paraformaldehyde Room and Biological Safety Cabinet Decontamination [UNMC - IBC14] policy. All IBC members listed as present voted with the following exceptions was absent from the room at the time of the vote.

IBC MINUTES

September 9, 2005 Meeting

Page 2

The IBC voted (9 in favor, 0 against, 1 abstention) to approve with minor revisions the Ultraviolet Lamp Safe Operation and Disposal [UNMC - IBC16] policy. All IBC members listed as present voted.

C. Incident and Event Reports

I informed the IBC about the adverse event regarding possible exposure of 2 outside contract personnel to a bio-hazardous agent. The IBC discussed at length the procedures that need to be carried out. [redacted] is scheduled to see the two outside contracted personnel on Monday, September 14, 2005. The IBC was concerned as to what type of follow-up procedures would be carried out. [redacted] stated he would talk with [redacted] as to the responsibilities of the IBC and any further information that stems from this event.

D. Special Notification and/or Review

No Reports

E. IBC Change in Protocol

No Reports.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 01-02-002-RL1

PI: [redacted] PhD

TITLE: Characterization of a Novel Glycosylation Pathway in Eukaryotes

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC # 01-10-010-BL1

PI: [redacted] hD

TITLE: Role of DNA Methylation in Altering Gene Expression during the Early Stages of Human Breast Cancer Progression in the MCF10AT Xenograft Model

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC # 04-10-045-BL1

PI: [redacted], MD

TITLE: A phase I/II study of an anti-tumor vaccination using a (1,3) galactosyltransferase expressing allogeneic tumor cells in patients with hormone refractory prostate cancer (IRB/SCR)

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC # 04-10-046-ABL1

PI: [redacted]

TITLE: Gene transfer to airway epithelial cells

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the ABL1 continuing review as submitted. All IBC members listed as present voted.

IBC MINUTES
September 9, 2005 Meeting
Page 3

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 02-10-024-ABL2

PI: [redacted] ID

TITLE: A role for viral infection in alcoholic pancreatitis

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the ABL2 continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-09-042-BL2

PI:

TITLE: Virulence of bla cmy-2 producing Salmonella

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room and did not participate in of the vote.

IBC #: 04-10-044-BL2

PI: [redacted]

TITLE: Regulation in HIV-1 associated dementia

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to conditionally approve the Application for Continuing Review pending receipt and acceptance of the following: (1) explain in more detail about the VSV-G protein and the effect it has on HIV-1 in Section IV of the continuing review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-11-049-BL3

PI: [redacted] ID

TITLE: Molecular genetics of Mycobacterium tuberculosis

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to conditionally approve the Application for Continuing Review pending receipt and acceptance of the following: (1) provision of written records that the investigator is doing viability and sterility on organisms. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC #: 04-11-050-BL2

PI: [redacted], MD

TITLE: Propagation and purification of large quantities of HIV-1

Outcome: The IBC voted (8 in favor, 0 against, 2 abstentions) to approve the BL2 continuing review as submitted. All IBC members listed as present voted.

IBC MINUTES

September 9, 2005 Meeting

Page 4

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

No proposals for review.

I. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC # 05-09-020-BL2




PI: [redacted]

TITLE: TRAIL and glutaminase: neurotoxic link in HIV-1 dementia

Outcome: The IBC voted (8 in favor, 0 against, 2 abstentions) to conditionally approve the BL2 pending receipt and acceptance of the following: (1) a letter of clarification in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

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

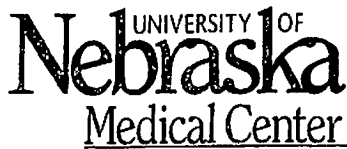
Respectfully Submitted,

Chair, IBC

OL/gdk

xc: [redacted], PhD
[redacted], MD
[redacted], PhD
[redacted], PhD



NEBRASKA'S HEALTH SCIENCE CENTER

INSTITUTIONAL BIOSAFETY COMMITTEE

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
August 12, 2005**

MEMBERS PRESENT:

ALTERNATE NON-VOTING PRESENT:

GUEST: S:

ADMINISTRATIVE STAFF PRESENT: None

He opened the meeting at 3:01 pm

A. Review and Acceptance of IBC Minutes

The July 8, 2005 minutes were accepted as written,

**B. Information, Education and Policy Items
Information**

He stated he reviewed a Public Health report which was distributed to the Board regarding the Tularemia incident. All points are covered within the IBC Application except for step #2 which has been added to the IBC Application for review at this meeting.

Update on OBA office procedures:

1. He discussed changes to the IBC application. He made changes to the animal section and made a revision to the Principal Investigator Assurance section. The IBC approved the revisions (7-1-0).

He informed the IBC that the routine CDC audit scheduled for August 9, 2005 was postponed by the CDC due to the fact that the BL3 facility in the DRC was not completed.

Samples from are distributed to the Board regarding exempt experiments. However, no discussion was held as the Board felt it would be better to discuss when F was in attendance. This item will be scheduled for the September meeting.

A satisfactory response letter from the NIH Office of Biotechnology Activities (7/20/05) accepting UNMC's response to OBA's request for additional information was distributed to the Board for their files.

A Quarterly Compliance Report – April 1 through June 30, 2005 was distributed to the IBC. This report is sent on behalf of the IBC to the UNMC Compliance Committee, chaired by

Discussion was held regarding HIV production from BL3 to BL2 for cultures less than 10 Liters. Cultures less than 10 Liters will be considered BL2.

IBC MINUTES
August 12, 2005
Page 2

informed the IBC that the Informational e-mails will be going out in the UNMC Today the week of August 15, 2005 and then again later this fall. The IBC had previously reviewed the content of the emails.

The IBC was notified that the Laboratory Advisory Committee held a meeting on July 27, 2005.

Education

The following educational items were distributed and key points discussed 1) Guest Article: IBCS, IRBS, and IACUCS: Creating a Stronger Foundation for the Oversight of Recombinant DNA Research. Allan C. Shipp, MHA; NIH Office of Biotechnology; ARENA Newsletter; Winter, 2003; Pages 4 – 5; and 2) Overview: The National Institutes of Health System for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research. Allan C. Shipp, MHA and Amy P. Patterson, MD; American Association for Laboratory Animal Science; April 2003; Pages 159 – 164.

Policy

The IBC voted (7 in favor, 0 against, 1 abstention) to approve with minor revisions the Autoclave Operation and Safety [UNMC – IBC-01] policy.

The IBC voted (7 in favor, 0 against, 1 abstention) to approve with minor revisions the Paraformaldehyde Room and Biological Safety Cabinet Decontamination [UNMC - IBC14] policy.

The IBC voted (7 in favor, 0 against, 1 abstention) to table the Ultraviolet Lamp Safe Operation and Disposal [UNMC - IBC16] policy. The IBC requested that more information regarding use of UV lamps for gel/blot analysis be added to the policy.

The IBC voted (7 in favor, 0 against, 1 abstention) to approve with minor revisions the Administration of IBC Protocols Involving Off-Site Laboratories [UNMC - IBC33] policy.

C. Incident and Event Reports

No incidents or events were reported.

D. Special Notification and/or Review

The IBC reviewed three protocols which involve training only
IBC #s: 03-00-023-BL3; 03-00-024-BL3-SA; and 03-00-025-BL2

PI: _____)

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve retaining the 3 training access protocols as submitted. All IBC members listed as present voted.

E. IBC Change in Protocol

No Reports.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 03-09-018-BL1

PI: _____, D

TITLE: Biochemical characterization of BRCA2

IBC MINUTES
August 12, 2005
Page 3

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the BL1 continuing review as submitted. All IBC members listed as present voted. A letter of approval will not be sent to the PI until all personnel are trained.

IBC # 03-09-019-BL1

PI:

TITLE: The roles of XPF/ERCC1 complex in DNA repair

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the BL1 continuing review as submitted. All IBC members listed as present voted. A letter of approval will not be sent to the PI until all personnel are trained.

IBC # 04-09-039-ABL1

PI:

TITLE: Transcriptional cofactors and tumorigenesis

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the ABL1 continuing review as submitted. All IBC members listed as present voted. A letter of approval will not be sent to the PI until all personnel are trained.

IBC # 04-09-041-BL1

PI:

TITLE: A phase III randomized, open-label study of

and in patients with metastatic hormone-refractory prostate cancer who are chemotherapy-naïve.

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC # 01-06-011-BL2

PI: L. H. H. D.

TITLE: Role of Protein Kinase C in Ischemic Renal Injury and Repair

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the BL2 continuing review as submitted. All IBC members listed as present voted.

IBC #: 02-08-020-ABL2

PI: I

TITLE: Nitric Oxide-Angiotensin Interaction on Baroreflex Function in Heart Failure

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the ABL2 continuing review following training approval for all personnel. All IBC members listed as present voted.

Note: On August 17, 2005, the investigator sent another continuing review completing this application prior to sending a re-approval letter; therefore, a letter was not sent. A copy of the email for completion is attached to the minutes.

IBC #: 03-10-027-BL2

PI:

TITLE: Utilization of the internal transcribed spacer sequences for the identification of fungal species

IBC MINUTES
August 12, 2005
Page 4

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the BL2 continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-08-037-ABL2

PI: , PhD

TITLE: Effects of chronic alcohol consumption on pulmonary infection with respiratory syncytial virus (RSV)

Outcome: The IBC voted (6 in favor, 0 against, 2 abstentions) to approve the BL2 continuing review as submitted. All IBC members listed as present voted.

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

No proposals for review.

I. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

No proposals for review.

There being no further business, adjourned the meeting at 3:50 p. m.

Respectfully Submitted,

Chair, IBC

OL/gdk

xc: PhD
MD, UNMC
PhD
uist, PhD, UNMC



NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
July 08, 2005**

MEMBERS PRESENT:

ALTERNATE NON-VOTING PRESENT:

ADMINISTRATIVE STAFF PRESENT: None

_____ led the meeting at 3:01 pm

A. Review and Acceptance of IBC Minutes

The June 8, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

Pete Iwen stated that there is no new information regarding the tularemia incident.

Update on ORA office procedures:

1. D_____ asked that the discussion on the revised IBC Section regarding transgenic animals be tabled until next month. Copies of the revised section will be sent out to the board for review prior to the August meeting.

_____ informed the IBC that a select agent team will perform a routine CDC inspection on August 9, 2005.

Further discussion was held regarding BL1 and exempt research _____ gave examples to the Board and stated he would put together a draft policy and algorithm to help the board distinguish between what is exempt from review and what falls under the BL1 category.

Education

No educational items were distributed this month.

Policy

The IBC voted (8 in favor, 0 against, 1 abstention) to table the Paraformaldehyde Room and Biological Safety Cabinet Decontamination [UNMC - IBC14] policy. The IBC requested the information regarding verification of acceptable decontamination be added to the policy.

The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve Administration of IBC Protocols Involving Off-Site Laboratories [UNMC - IBC33] policy pending review and approval from _____. This policy will go back to the IBC for final approval.

IBC MINUTES

July 08, 2005

Page 2

C. Incident and Event Reports

The IBC was notified regarding a Mycobacterium tuberculosis spill in a BL3 facility. This spill occurred in a clinical laboratory facility during routine clinical duties. No specific protocol was involved in this spill and the lab personnel involved will have a follow up skin test in six months. It was determined that this incident required reporting to the appropriate clinical oversight individuals via the Employee Incident Reporting Form. The incident did not require reporting to the IBC which oversees research activities only.

D. Special Notification and/or Review

None

E. IBC Change in Protocol

None.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 02-08-019-BL1

PI

TITLE: #1. DNA Binding and Expression of Elf-3. #2. Structure and Function of the Transcription Factor Elf-3.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC # 04-09-040-ABL1

PI: S. ~ 'hD

TITLE: Bioengineering of the blood-brain permeability for drugs

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted. A letter of approval will not be sent to the PI until all personnel are trained.

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 02-09-021-ARI 2

PI: ~ ~ ~

TITLE: In vivo analyses of OTK18 gene function

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the ABL2 continuing review pending completion of training by personnel. All IBC members listed as present voted. A letter of approval will not be sent to the PI until all personnel are trained.

IBC MINUTES

July 08, 2005

Page 3

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 05-07-016-BL1

PI: A D

TITLE: 1) The role of inositol metabolism in neurodegeneration. 2) High throughput positional cloning of mouse neurological mutants. 3) Cell specific cDNA libraries

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1. All IBC members listed as present voted.

I. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 05-07-017-BL2

PI:

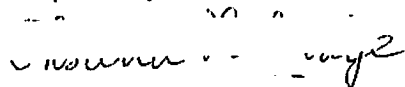
TITLE: Tigecycline Evaluation and Surveillance Trial (T.E. S. T)

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the BL2. All IBC members listed as present voted with the following exceptions 1) Paul Fey was excused from the meeting and did not participate in the discussion or vote.

There being no further business

adjourned the meeting at 3:55 p. m.

Respectfully Submitted,



Chair, IBC

OL/gdk

xc:

id

is, MD, UNMC

PhD

, PhD, UNMC

MEMBERS PRESENT:

ALTERNATE NON-VOTING PRESENT:

ADMINISTRATIVE STAFF PRESENT: None

opened the meeting at 3:01 pm

A. Review and Acceptance of IBC Minutes

The May 13, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

1 informed the IBC that discussion regarding the tularemia incident continues and that CDC testing is now being performed.

Update on ORA office procedures:

1. D provided the IBC with a revised IBC Section of the initial application to better solicit required information regarding transgenic animals. The IBC conditionally approved the revisions, requested additional revisions, and all changes will be made by the ORA office and the revised form will be returned to the board for review.
2. informed the board that she is not able to change any of the agent classification boxes in the database. y will contact IT.
3. Discussion was held regarding BL 1 and exempt research will add examples to the NIH intranet site 1 page description "Guidelines to the Guidelines" for use as a tool for the researchers and IBC.

1 informed the Board that UNO submitted the information on researchers involved in Recombinant DNA per the May 16, 2005 memo from.

stated that the response letter to OBA dated June 8, 2005 was mailed and a copy for each Board member is attached.

Education

The following educational items were distributed and the key points discussed: 1) Tularemia Probe Expands to UNMC. Bill Hord; Omaha World Herald; Tuesday May 17, 2005; 2) Guideline to the Guidelines - Outline to serve as a guide to the NIH Guidelines for Recombinant DNA Research. April 1999; 3) Vaccinia (Smallpox) Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. John F. Modlin, MD; Recommendations and Reports - June 22, 2001; and 4) UNMC Institutional Biosafety Committee (IBC) - The ABCs of IBCs. Three draft notices to UNMC Today for IBC educational purposes. The Board was asked to review and send any comments on the educational items to the ORA Office.

IBC MINUTES

June 10, 2005

Page 2

Policy

The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Biohazardous Waste Disposal [SOP#UNMC-IBC05] policy with minor revisions.

The IBC voted (9 in favor, 0 against, 1 abstention) to approve Centrifuge Safe Operation [SOP#UNMC-IBC07] with minor revisions.

The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Immunization Policy for Research Using Vaccinia Virus [SOP#UNMC-IBC13] which will facilitate the process for obtaining vaccine for individuals wishing to be vaccinated per the policy.

C. Incident and Event Reports

None

D. Special Notification and/or Review

None

E. IBC Change in Protocol

The IBC reviewed the following requests for change in order to ensure the amended research protocol continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer and in the IBC Guidelines.

IBC #: 03-04-011-ABL2

PI: [redacted], PhD

TITLE: Function of the PVN in heart failure: role of NO and NMDA, Normalization of enhanced NMDA receptor-mediated sympathetic outflow in heart failure: effect of nNOS gene transfection into the PVN.

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the change as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC #: 02-07-017-BL 1

PI: [redacted], PhD

TITLE: Structure Studies on Replication Protein a and Rad52

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted.

IBC #: 04-07-035-BL1

PI: [redacted], PhD

TITLE: The roles of IRF4,8 in pre-B cell development.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC MINUTES

June 10, 2005

Page 3

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC #: 01-00-012-BL2

PI: [redacted] PhD

TITLE: 1)Contribution of Mdm2 to Lymphoma; 2) Role of Mdm2 in Lymphoma Development; 3) Mdm2 Overexpression in Lymphoma; 4)p53-Independent Oncogenic Functions of Mdm2

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC#: 02-07-016-BL2

PI: Li MD, PhD

TITLE: Regulation of T-Cell Homeostasis by Heparin-Sulfate Bound IL-2

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC #: 03-05-012-ABL2

PI: [redacted], PhD

TITLE: Augmenting innate and vaccine immune response with derG.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the ABL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] was absent from the room at the time of the vote.

IBC#: 03-07-013-BL3-SA

PI: [redacted] hD

TITLE: Immune responses to Francisella Tularensis

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the BL3 continuing review as submitted. All IBC members listed as present voted with the following exceptions 1) V [redacted] e was absent from the room at the time of the vote; 2) [redacted] n was excused from the meeting and did not participate in the discussion or vote.
voting

IBC #: 03-07-015-BL2-SA

PI: [redacted] MD

TITLE: Centers for Disease Control and Prevention-Laboratory Response Network Level-C Diagnostic Testing for Clostridium botulinum toxin

Outcome: The IBC voted (7 in favor, 0 against, 2 abstentions) to approve the BL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions 1, [redacted] was absent from the room at the time of the vote

IBC #: 04-06-034-BL2

PI: T PhD

TITLE: Immortalization of human bronchial epithelial cells by SV40 LT.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL2 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) V [redacted] was absent from the room at the time of the vote.

IBC MINUTES

June 10, 2005

Page 4

IBC #: 04-07-036-ABL2

PI: [REDACTED]

TITLE: Gene therapy in the induction of transplant tolerance

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 continuing review as submitted. All IBC members listed as present voted with the following exceptions: 1) Wanda Clarke was absent from the room at the time of the vote.

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC: 05-05-014-RI 1

PI:

TITLE: 1) Genetic susceptibility to estrogen-induced mammary cancer; 2) Genetic etiology of renal agenesis in the ACI rat; 3) Hormonal, genetic and epigenetic determination of mammary cancer susceptibility; 4) Genetic and environmental determinants of estrogen action in the pituitary gland.

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1. All IBC members listed as present voted with the following exceptions: 1) [REDACTED] was absent from the room at the time of the vote.

I. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC: 05-05-015-ABL2

PI: [REDACTED] PhD

TITLE: Neuroprotective effect of autoimmune T cells in a mouse model of HIV-associated dementia (HIVD).

Outcome: The IBC voted (9 in favor, 0 against, 1 abstention) to conditionally approve the ABL2 pending receipt and acceptance of the following: (1) a letter of clarification in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

There being no further business, Dr. [REDACTED] adjourned the meeting at 4:20 p. m.

Respectfully Submitted,

[REDACTED]
[REDACTED] PhD

Chair, IBC

OL/gdk

xc: [REDACTED] PhD
[REDACTED] MD, UNMC
[REDACTED] PhD
[REDACTED] PhD, UNMC

BIOSAFETY PROGRAM

MEMBERS PRESENT: [illegible] Steve Dixon, Paul Fox
[illegible]
[illegible]

ADMINISTRATIVE STAFF PRESENT: None

A. Review and Acceptance of IBC Minutes

A. Review and Acceptance of IBC Minutes
The April 8, 2005 minutes were accepted with a request to clarify the decision to delete a requirement for a progress report from the Application for Continuing Review under ORA procedures/Point #1.

B. Information, Education and Policy Items

Information

information
[redacted] informed the IBC that [redacted] had stated discussion regarding the tularemia incident continues.

Update on ORA office procedures:

1. [redacted] will review and bring back for discussion at the June 2005 IBC meeting a revised IBC Section of the initial application to better solicit required information regarding transgenic animals. [redacted] provided him with several examples of how other IBC's address this requirement.

10 informed the Board that she met with [redacted] 1. The two of them reviewed the draft tracking sheet being developed to assist UNO investigators in providing IBC approval for studies submitted to the UNO sponsored programs office.

An update on the mechanisms for IBC review of studies from investigators at the College of Dentistry in Lincoln was presented by [redacted]. The COD is part of UNMC but physically located in Lincoln. She had met with [redacted]. [redacted] felt that the UNMC IBC should contact the UNL IBC to negotiate a similar lab inspection and IBC review process being done for this college with regards to the IACUC. Documentation of training could be provided to UNMC as required.

A follow up letter dated May 6, 2005 from the Office of Biosafety was distributed and discussed with the IBC. E stated that OBA is requesting further documentation on protocols from 2002 up to the present. She is also putting together a survey to confirm which investigators are involved in Recombinant DNA both on the UNMC campus as well as UNO. Revised policies were on the agenda for IBC review in response to suggestions from OBA.

IBC MINUTES

April 08, 2005

Page 2

Education

The following educational item was distributed and the key points discussed: Biosafety Committees Come Under Scrutiny. Kelly Field; The Chronicle of Higher Education; April 20, 2005; 5 pages.

Policy

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Biological Incident/Spill Clean-up [SOP#UNMC-IBC04] policy.

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Biosafety Training Program [SOP#UNMC-IBC06] policy with minor revisions.

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the IBC Application & Review Process for New Protocols [SOP#UNMC-IBC08].

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the IBC Laboratory Inspection Process [SOP#UNMC-IBC11]. .

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the IBC Review Process of Previously Approved Protocols [SOP#UNMC-IBC12] policy.

The IBC voted (10 in favor, 0 against, 1 abstention) to table the Immunization Policy for Research Using Vaccinia Virus [SOP#UNMC-IBC13]. The Board tabled this policy until Dr. Hinrichs and _____ can meet and provide guidance to the IBC.

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Laboratory Decommissioning Policy [SOP#UNMC-IBC17].

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Laboratory Commissioning – BSL2 [SOP#UNMC-IBC19].

The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Laboratory Commissioning – BSL3 [SOP#UNMC-IBC20].

C. Incident and Event Reports

The IBC voted (10 in favor, 0 against, 1 abstention) that the spill incident appeared to have been properly contained and decontamination procedures were appropriate. The individual was referred to Employee Health. Employee Health required a repeat chest x-ray in 10 -12 weeks. The incident will be reviewed again at that time. The IBC determined that the incident did not meet reporting requirements of a significant research related accident or illness per NIH guidelines at IV.B-1-j and IV-B-2-b-(7) at this time.

D. Special Notification and/or Review

None

E. IBC Change in Protocol

The IBC reviewed the following requests for change in order to ensure the amended research protocol continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer and in the IBC Guidelines.

None

F. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

None

G. IBC Continuing Review of BL2 and BL3 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC#: 03-03-007-ABL2 **PI:** [redacted], MD, PhD

TITLE: Overcoming Tumor Escape by Survivin Vaccine

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] and [redacted] were absent from the room at the time of the vote.

IBC#: 03-09-021-ABL2 **PI:** [redacted], PhD

TITLE: Immunotherapy for breast cancer; SLC and Flt3L as potential therapies for breast cancer

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] and [redacted] were absent from the room at the time of the vote.

IBC#: 04-01-001-BL2 **PI:** [redacted], PhD

TITLE: MHC Class I presentation of influenza A and Listeria monocytogenes epitopes

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] and [redacted] were absent from the room at the time of the vote.

IBC#: 04-06-032-ABL2 **PI:** [redacted], PhD

TITLE: Generating human non-polio enterovirus and rhinovirus vectors for antigens and interleukins

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] and [redacted] were absent from the room at the time of the vote.

IBC#: 04-06-034-BL2 **PI:** [redacted], PhD

TITLE: Immortalization of Human Bronchial Epithelial Cells by SV40 LT

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to Table the Continuing Review. The IBC noted that the IBC Continuing Review Application refers to transportation of tissues from animals previously infected with RSV. However, this protocol was originally approved for use of SV40 CT, not RSV. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: [redacted] and [redacted] were absent from the room at the time of the vote.

H. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC#: 05-05-012-BL1 FI: er, PhD
TITLE: Experimental surgical technology-Freehand navigated (computer assisted) total knee replacement

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 submitted. All IBC members listed as present voted with the following exceptions: 1 [redacted] and [redacted] were absent from the room at the time of the vote.

IBC#: 05-05-013-BL1 PI: [REDACTED] ng, PhD
TITLE: Structural Biology of a Bacterial Signal Transduction Pathway; Structures of MUC1;
Structure of Antimicrobial and Anticancer Peptides by NMR

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the BL1 submitted. All IBC members listed as present voted with the following exceptions: 1) [redacted] and [redacted] were absent from the room at the time of the vote.

I. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC#: 05-04-011-BL2 PI: I, PhD
TITLE: Prokaryotic mRNA half-life studies

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to conditionally approve the BL2 pending receipt and acceptance of the following: (1) a revised IBC Application informing the IBC that personnel will be trained to report any biological spill to the PI; and that any spills involving the contamination of personnel and/or the environment that has the potential to cause illness or may cause sufficient concern to the public will be reported to the IBC in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: 1) _____ and _____ were absent from the room at the time of the vote.

There being no further business, _____ he adjourned the meeting at 4:29 p. m.

Respectfully Submitted,

Chair, IBC

OL/gdk

xc: 7hd
3, MD, UNMC
...ue, PhD
7hd, UNMC

NEBRASKA'S HEALTH SCIENCE CENTER

MEMBERS PRESENT:

ADMINISTRATIVE STAFF PRESENT: None

A. Review and Acceptance of IBC Minutes
The March 11, 2005 minutes were accepted as written.

_____ welcomed _____ MD, from the section of Oncology/Hematology as a new IBC board member.

n gave a brief update discussion regarding the tularemia incident. The main point was that the FBI is now involved.

Dr. [REDACTED] updated the Committee on Biosafety at UNO. [REDACTED] and the Sponsored Programs Office are developing a coversheet to track whether IBC approval is required. [REDACTED] is working on some information emails to educate investigators and staff on the need for IBC approval for projects involving recombinant DNA and infectious agents.

§ 87(2)(b) informed the IBC that § 87(2)(b) has agreed to have his protocol used as a model for other investigators. § 87(2)(b) will work on modifying to remove any identifiers and submit to § 87(2)(b) to be posted on the IBC website.

1. The board discussed the revised Continuing Review Form submitted to all IBC members. The board felt the changes were appropriate. They also discussed why a progress report was required when no changes were made to the study. It was decided to eliminate the progress report. If changes were made, information will already be provided. The Continuing Review email will be revised with this new form and the form will also be posted on the website.

2. informed the board that quarterly lab inspection reports must be submitted to the compliance committee on campus. y will work with IT to design the appropriate report.

He then updated the Committee on the DRC facilities. The BL3 lab on the 8th floor of the DRC will be approved the week of April 11, 2005 as the air handling system issues have been resolved.

Education

The following educational item was distributed and the key points discussed: Introduction to the National Institutes of Health Office of Biotechnology Activities. Allan Shipp; Slide Presentation; 10 pages.

Policy

The IBC voted (09 in favor, 0 against, 1 abstention) to approve the Autoclave Operation and Safety [SOP#UNMC-IBC01] policy with minor revisions. [Name] was absent for the vote.

The IBC voted (09 in favor, 0 against, 1 abstention) to approve the Biological Safety Cabinet Certification [SOP#UNMC-IBC02] policy with minor revisions. [Name] was absent for the vote.

The IBC voted (09 in favor, 0 against, 1 abstention) to approve the Biological Safety Cabinet Operation [SOP#UNMC-IBC03]. [Name] was absent for the vote.

The IBC voted (09 in favor, 0 against, 1 abstention) to conditionally approve the Biological Incident/Spill Clean-up [SOP#UNMC-IBC04] policy. This policy will be revised and brought back for further review at the May 2005 IBC meeting. [Name] was absent for the vote.

The IBC voted (09 in favor, 0 against, 1 abstention) to approve the IBC Application and Review Process for New Protocols [SOP#UNMC-IBC08]. The Board approved this previously approved policy to clarify procedures for review of BL1 studies. [Name] was absent for the vote.

The IBC voted (09 in favor, 0 against, 1 abstention) to approve the IBC Policy and Procedure Approval Process [SOP#UNMC-IBC31]. Initial review was performed at 3/11/05 IBC meeting and further revisions made for re-review. [Name] was absent for the vote.

The IBC voted (09 in favor, 0 against, 1 abstention) to approve the Federal Permits for the Shipment of Human Pathogens [SOP#UNMC-IBC32]. [Name] was absent for the vote.

C. Special Notification and/or Review

None

D. IBC Change in Protocol

The IBC reviewed the following requests for change in order to ensure the amended research protocol continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer and in the IBC Guidelines.

None

E. IBC Continuing Review of BL1 Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review for research designated as BL-1. Any identified errors, deficiencies or other problems were noted and resolved. The IBC voted to approve the continuation of these projects. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC MINUTES

April 08, 2005

Page 3

IBC# 02-05-013-BL1 **PI:** , PhD

TITLE: Molecular Studies on MIC-1 Gene

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted

IBC# 04-05-022-BL1 **PI:** , PhD

TITLE: 1) Role of ryanodine receptors in diabetic cardiomyopathy. 2) Role of SERCA2a in diabetic cardiomyopathy

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted

IBC# 04-05-024-BL1 **PI:** PhD

TITLE: Assessment of Cell Signaling

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted

F. IBC Continuing Review of Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC#: 01-10-015-BL2 **PI:** , PhD

TITLE: BDNF induced drug resistance in Neuroblastoma

Outcome: The IBC voted (09 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted with the following exceptions: 1) was absent from the room at the time of the vote.

IBC#: 04-05-025-ABL3-SA **PI:** , PhD

TITLE: Immune responses after pulmonary infection by Francisella tularensis subspecies tularensis or Coxiella burnetii Ninemile phase I

Outcome: The IBC voted (09 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. All IBC members listed as present voted with the following exceptions: 1) was absent from the room at the time of the vote.

G. IBC Research Proposals and/or 5-year Rewrites

The IBC members were notified regarding a BL1 application for initial review and/or 5-year rewrites that was reviewed by the IBC Chair and will be approved following notification to the IBC, and the IBC's approval to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC#: 05-03-010-BL1 **PI:** / ad, PhD

TITLE: Mesenchymal transitions in head and neck tumors

Outcome: The IBC voted (10 in favor, 0 against, 1 abstention) to approve the BL1 submitted. All IBC members listed as present voted.

IBC MINUTES

April 08, 2005

Page 4

H. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

None

There being no further business

adjourned the meeting at 4:03 pm.

Respectfully Submitted,



Chair, IBC

OL/gdk

xc:

UNMC

PhD

PhD, UNMC



NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
March 11, 2005**

MEMBERS PRESENT:

ise

ALTERNATES NON-VOTING PRESENT: None

ADMINISTRATIVE STAFF PRESENT: None

opened the meeting at 3:00 pm

A. Review and Acceptance of IBC Minutes

The February 11, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

An updated discussion regarding the tularemia incident was presented by . The controversy continues, and will continue to update the board monthly until resolution occurs.

reported that they met with the Biosafety Officer from UNO. UNO is planning email messages and other educational approaches to educate the UNO community regarding requirements for IBC review.

announced that e has agreed to serve on the IBC.

in noted that she will be attending a national IBC meeting presented by the Office of Biotechnology Affairs on Sunday, March 13, 2005 in San Diego, California.

nn updated the Committee on progress in establishing study specific files in ORA. Files for studies being reviewed at each meeting will be brought to the IBC meeting for reference. Access to the files is always available to Committee members in the ORA office. I forward electronic copies of all final BL-1 projects to ORA for inclusion in the file.

made the application a fillable form, and it is posted on the website.

n suggested that the CR form be revised to request current laboratories used, and 2) Comparative Medicine rooms used.

Education

The following educational items were distributed and the key points discussed: 1) Recombinant DNA Advisory Committee: Recombinant DNA and Gene Transfer. January 31, 2005; Pages 1 - 2; and 2) Frequently Asked Questions: Recombinant DNA and Gene Transfer. January 31, 2005; Pages 1 – 11.

Policy

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Shipping and Receiving of Category A High Consequence Pathogens [SOP#UNMC-IBC30] policy with minor revisions.

The IBC Policy and Procedure Approval Process [SOP#UNMC-IBC31] will be revised to clarify that the most current version of policies will reside in the Office of Regulatory Affairs to reduce chances that an outdated policy would be use for revision.

C. Special Notification and/or Review

o notified the IBC regarding an IRB review of an unexpected event on a vaccine study for an infectious agent, *Mycoplasma*. suggested that this report in review be accepted in lieu of a separate report to the IBC and the IBC voted (08 in favor, 0 against, 1 abstention) to accept

Investigator: d, MD

Title: Adenovirus p53 Infected DC Vaccine for Breast Cancer (SRC & IBC)

D. IBC Change in Protocol

The IBC reviewed the following requests for change in order to ensure the amended research protocol continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer and in the IBC Guidelines.

None

E. IBC Continuing Review of BL1 Active Research by Expedited Review

The IBC members were notified regarding expedited review of requests to continue research designated BL-1. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 03-04-010-BL1

PI:

TITLE: Triplet repeat instability in cultured human cells

IBC# 04-05-026-BL1

PI:

TITLE: 1) Regulation of growth factors and embryogenesis. 2) Inactivation of the k-FGF-4 gene embryonic stem cells

F. IBC Continuing Review of Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC#: 03-04-011-BL2

PI: ..

TITLE: Function of the PVN in heart failure: role of NO and NMDA, Normalization of enhanced NMDA receptor-mediated sympathetic outflow in heart failure: effect of nNOS gene transfection into the PVN.

Outcome: The IBC voted (07 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: 1) _____ was absent from the room at the time of the vote.

IBC#: 04-03-008-ABL2

PI: -

TITLE: Genetic vaccines for cancer

Outcome: The IBC voted (07 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: 1) _____ was absent from the room at the time of the vote.

IBC#: 04-04-015-ABL2

PI:

TITLE: Regulation of antigen presentation

Outcome: The IBC voted (07 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: 1) _____ was absent from the room at the time of the vote.

G. IBC Research Proposals and/or 5-year Rewrites Reviewed by Expedited Review

The IBC members were notified regarding an application for initial expedited review and/or 5-year rewrites that was approved.

IBC#: 05-03-007-BL1

PI:

TITLE: Genetic effects of overexpression of human RNA/DNA editing deaminases

H. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 05-03-008-BL3

PI: .

TITLE: Protein profile analysis of select agents and relevant comparators

Outcome: The IBC voted (6 in favor, 0 against, 3 abstentions) to conditionally approve the proposal pending receipt and acceptance of the following: (1) a revised IBC Application/letter of clarification in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 05-03-009-BL2

PI:

TITLE: PDGF receptor signaling in neural stem cells

Outcome: The IBC voted (7 in favor, 0 against, 1 abstention) to approve the proposal. A letter will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted with the following exceptions: 1) _____ was absent from the room at the time of the vote.

There being no further business,

adjourned the meeting at 3:47 pm.

Respectfully Submitted,

, PhD

Chair, IBC

OL/gdk

xc:



NEBRASKA'S HEALTH SCIENCE CENTER

BIOSAFETY PROGRAM

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
February 11, 2005**

MEMBERS PRESENT:

A

ALTERNATES NON-VOTING PRESENT:

ADMINISTRATIVE STAFF PRESENT: None

opened the meeting at 3:03 pm

A. Review and Acceptance of IBC Minutes

The January 11, 2005 minutes were accepted as written.

B. Information, Education and Policy Items

Information

The response letter to OBA dated January 24, 2005 was distributed to IBC members.

The IBC discussed registration requirements for BL3 protocols. The concerns stemmed from the IBC's previous discussion and copies of UNMC IBC's request for justification when IBC protocol 04-12-055 was reviewed in January. After discussion by many members of the board, they agreed to approve the general safety protocols for the university. The IBC will draft a policy to provide review for these protocols.

discussed the tularemia incident at Boston University. He and met with people from Lincoln regarding this incident. It was felt that the site in Lincoln was not at fault, but this issue will continue to be investigated, and will continue to update the board monthly until resolution occurs.

Education

The following educational items were distributed and the key points discussed: 1) Safety Considerations in Recombinant DNA Research with Pathogenic Viruses. Recombinant DNA and Gene Transfer; Office of Biotechnology Act; OBA Safety Symposium; September 2004; 2) NIH Guidelines: Section I. Scope of the NIH Guidelines; and 3) NIH Guidelines: Section IV. Role and Responsibilities.

Policy

The IBC voted 8 for, 0 against, 1 abstention on the following actions:

- 1) If a protocol is conditionally approved or approved with modifications then these changes may go back to the IBC chair for re-review.
- 2) If a protocol is tabled or disapproved, then the modifications/changes must go back to the next regularly convened IBC meeting and if possible back to the initial reviewers.

The IBC was notified regarding the approval of the Reporting of Research Related Adverse Events policy. The Board voted by email (11 in favor, 0 against, 0 abstentions). An AE form has been developed by [redacted] with modifications required. [redacted] completed these changes. She will forward the form to Tuire Cechin who has agreed to help make a "fillable" form.

C. IBC Change in Protocol

The IBC reviewed the following requests for change in order to ensure the amended research protocol continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer and in the IBC Guidelines.

None

D. IBC Continuing Review of BL1 Active Research by Expedited Review

The IBC members were notified regarding expedited review of requests to continue research designated BL-1. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 02-03-009-BL1 **PI:** [redacted] PhD

TITLE: 1. Lysophosphatidic acid and its receptors in health and disease. 2. Lysophosphatidic acid and smoking-related airway disease. 3. Lysophosphatidic acid as a mediator in asthma. 4. Regulation of lung cell EGF receptor expression by GPCRs.

IBC# 03-03-003-BL1 **PI:** [redacted] PhD

TITLE: Endogenous Ligands of Galectin-3 in Cancer Cells

IBC# 04-02-006-BL1 **PI:** [redacted] PhD

TITLE: 1) Mutagenesis mediated by lesion bypass DNA polymerases. 2) Role of DNA polymerases in chromosome stability control. 3) Mechanisms of mutagenesis mediated by translesion synthesis DNA polymerase.

IBC# 04-03-009-BL1 **PI:** [redacted] PhD

TITLE: Gene therapy of lung cancer

IBC# 04-04-016-BL1 **PI:** [redacted] PhD

TITLE: Nebraska Center for Cellular Signaling: The role of desmosomes in oral squamous cell carcinoma

E. IBC Continuing Review of Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer or in the IBC Policies.

IBC#: 87-00-001-BL2 **PI:** [redacted] PhD

TITLE: Molecular basis for ectopic gene expression in tumors

Action: Pulled from review. PI is doing a 5 year rewrite.

IBC#: 02-04-010-ABL2 **PI:** , PhD
TITLE: Enterovirus presence in myocarditis and idiopathic dilated cardiomyopathy persistence through deleted geneomes
Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 03-03-005-BL2 **PI:** , PhD
TITLE: 1) Role of ERK1/2 Signaling in BRCA1-Mediated G2/M Arrest. 2) ERK/2 signaling in BRCA1-mediated DNA damage response.
Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 04-03-010-ABL2 **P:** le, PhD
TITLE: Role of astroglial activation in chronic inflammatory neurodegenerative diseases
Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 04-03-011-BL2 **PI:** M, hD
TITLE: 1) Regulation of lung cell EGF receptors by GPCRs; 2) G protein-coupled receptor regulation of EGF receptors; 3) G protein-coupled receptor modulation of lung cell EGF receptor expression and function; 4) Opposite regulation of epidermal growth factor receptors by G protein coupled receptors in airway smooth muscle cells.
Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 04-03-014-ABL2 **PI:** , PhD
TITLE: Transduction of stem cell and elated cell populations with marker, selection and gene silencing vectors followed by assay of in vitro and in vivo effects.
Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

F. IBC Research Proposals and/or 5-year Rewrites Reviewed by Expedited Review
The IBC members were notified regarding an application for initial expedited review and/or 5-year rewrites that was approved.

IBC# 05-01-003-BL1 **PI:** 'hD
TITLE: Mechanisms of Bax Activation.

G. IBC Initial Review of Research Proposals
The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC#: 04-12-055-BL3 (previously tabled at 1/14/05 IBC Meeting)

PI:

TITLE: United States National Domestic Preparedness Program (Originally approved 02-23-2000; IBC #00-00-017)

Outcome: The IBC voted (7 in favor, 0 against, 2 abstentions) to approve the proposal. A letter will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 05-01-005-BL2 (new submission)

PI: [redacted] Id, PhD

TITLE: Molecular Dissection of IGF2R Growth Suppressor Activity (1) And Insulin-like Growth Factor Binding Protein-6 and Prostate Cancer (2)

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the proposal. A letter will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 05-02-006-ABL2 (new submission)

PI: [redacted] PhD

TITLE: Macrophages, Neuronal K channels and HIV-1-associated Dementia

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the proposal. A letter will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

There being no further business, [redacted] adjourned the meeting at 3:45 pm.

Respectfully Submitted,

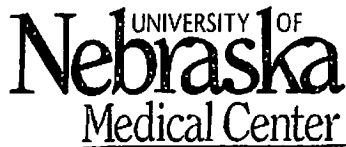
Chair, IBC

OL/gdk

xc:

[redacted] es, MD, UNMC
[redacted] PhD

UNMC



NEBRASKA'S HEALTH SCIENCE CENTER

BIOSAFETY PROGRAM

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
January 14, 2005**

MEMBERS PRESENT:

:
:

ALTERNATES NON-VOTING PRESENT:

ADMINISTRATIVE STAFF PRESENT: None

opened the meeting at 3:05 pm

A. Review and Acceptance of IBC Minutes

The December 10, 2004 minutes were accepted as written.

B. Information, Education and Policy Items

Information

The IBC received a copy of a letter from OBA dated 12/15/04. informed the Board that she and were working on a response to each of the concerns to be transmitted on behalf of UNMC by in University of Nebraska Central Administration. and were going to Lincoln on Friday, January 7, 2005 to meet with representatives of UNL and Central Administration regarding the response.

A memo from OBA dated 12/6/04 regarding Recombinant DNA Research and IBC was distributed to the IBC for their information.

Education

The following educational item was distributed and the key points discussed: 1) Recent Developments in Gene Transfer: Risk and Ethics. Jonathan Kimmelman; British Medical Journal; Volume 330; January 8, 2005; Pages 79 – 82.

Policy

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Reviewer Assignments policy as submitted.

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Consultants policy as submitted.

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Membership policy as submitted.

IBC MINUTES

January 14, 2005

Page 2

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Quorum and Voting policy with the addition of clarification of voting requirements. It was noted that this Committee will use a simple majority voting policy.

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Application and Review Process for New Protocols policy as submitted.

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Application and Review Process for Protocols Involving Human Gene Transfer Experiment policy as submitted.

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Application and Review Process for New Protocols Utilizing a Select Agent policy as submitted.

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the IBC Review Process for Previously Approved Protocols policy as submitted.

The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Personnel Access for Biosafety Level 3 Containment Laboratory policy as submitted.

The IBC voted (08 in favor, 0 against, 1 abstention) to conditionally approve the Reporting of Research Related Adverse Events draft policy as submitted. The IBC requested revisions to the draft policy. The revised draft will be distributed via email for review and voting.

presented a summary of the IBC Subcommittee Meeting held January 7, 2005. The IBC accepted the recommendations of the subcommittee.

C. IBC Change in Protocol

The IBC reviewed the following requests for change in order to ensure the amended research protocol continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer and in the IBC Guidelines.

None

D. IBC Continuing Review of BL1 Active Research by Expedited Review

The IBC members were notified regarding expedited review of requests to continue research designated BL-1. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 02-02-008-BL1 **PI:** PhD

TITLE: 1. Mechanisms of desensitization of adrenergic receptors. 2. Caveolar localization, function and regulation of alpha-1 adrenergic receptors. 3. Upregulation of G-protein mutated alpha-1 adrenergic receptors by protection from inherent instability

IBC# 04-02-005-BL1 **PI:** PhD

TITLE: 1) Structure -function of novel enzyme sanitizing dNTP pools. 2) Mechanisms of targeting of DNA metabolism proteins involved in humoral and innate immunity

E. IBC Continuing Review of Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below. Continuing review was performed using the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC#: 03-03-009-BL2 **PI:** [redacted], MD, PhD

TITLE: Test system for HIV-1 vaccine evaluation.

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 04-03-012-ABL2 **PI:** [redacted], MD

TITLE: Human/pig Hybrid Model of Hepatitis C Virus for New Vaccines

Outcome: The IBC voted (08 in favor, 0 against, 1 abstention) to approve the Continuing Review as submitted. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

F. IBC Research Proposals and/or 5-year Rewrites Reviewed by Expedited Review

The IBC members were notified regarding an application for initial expedited review and/or 5-year rewrites that was approved.

IBC# 05-01-001-ABL1 **PI:** [redacted] Ph.D.

TITLE: Gene Therapy of Prostate Cancer

IBC# 05-01-002-BL1 **PI:** [redacted] PhD

TITLE: Regulation of Human Prostatic Acid Phosphatase

Signaling in Androgen-Refractory Prostate Cancer

Signaling in Human Prostate Neuroendocrine Cells

G. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC#: 04-12-053-BL2 **PI:** [redacted] PhD

TITLE: Transfection of endocytic recycling regulatory proteins

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to approve the proposal. A letter will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC#: 04-12-054-BL2 **PI:** [redacted] PhD

TITLE: Signaling mechanisms in the ovary

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to table the proposal pending receipt of more detailed information regarding the purpose and methods of this study. The investigators response must be reviewed by the original reviewers. A letter detailing the specific points that the IRB asked the PI to address will be sent and reflected in Addendum I to the minutes. IBC members listed as present voted.

IBC MINUTES

January 14, 2005

Page 4

IBC#: 04-12-055-BL3 PI: , PhD

TITLE: United States National Domestic Preparedness Program

(Originally approved 02-23-2000; IBC #00-00-017)

Outcome: The IBC voted (8 in favor, 0 against, 1 abstention) to table the proposal. The IBC requested clarification of the rationale for requiring IBC review for what appeared to be clinical activities. The Committee also requested clarification of whether some materials are RG2 rather than RG3. A letter detailing the specific points that the IRB asked the PI to address will be sent and reflected in Addendum I to the minutes. IBC members listed as present voted.

There being no further business, adjourned the meeting at 4:20 pm.

Respectfully Submitted

David C. Gross, PhD
Chair, IBC

OL/gdk

xc: David C. Gross, PhD
, MD, UNMC
PhD
, PhD, UNMC



NEBRASKA'S HEALTH SCIENCE CENTER

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
December 10, 2004**

MEMBERS PRESENT:

ALTERNATES NON-VOTING PRESENT:

ADMINISTRATIVE STAFF PRESENT: None

opened the meeting at 3:10 pm

A. Review and Acceptance of IBC Minutes

The November 12, 2004 minutes were accepted pending the revision of the correct voting for 04-11-047-BL2 from 10-0-1 to 9-0-2 as abstained from voting since he is a secondary investigator.

B. Information, Education and Policy Items

Information

informed the IBC that appointment letters will be mailed out to all members.

asked for verification of the IBC's training policy regarding BL-1 studies. The Board confirmed that verification of BL-1 training is not required prior to release of the protocol.

Education

None

Policy

Discussion was held regarding the renewal frequency for online training for biosafety. Would it be appropriate for training to be retaken once every three years rather than once every year. After a lengthy discussion, the board voted 8-1-1 to approve the policy that investigators and participating personnel on BL1 and BL2 protocols are required to renew the online training every 3 years. The Board voted 8-1-1 that investigators and participating personnel on all BL3 protocols and all select agent protocols must renew the online BL3 and select agent training every year. The basic modules must be renewed every three years.

C. IBC Change in Protocol

The IBC reviewed the following requests for change in order to ensure the amended research protocol continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer and in the IBC Guidelines.

IBC# 04-05-018-BL2; PI: ; TITLE: Blood-brain Barrier Physiology and HIV Dementia. The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Request for Change as submitted requesting reclassification from BL3 to BL2. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC MINUTES
December 10, 2004
Page 2

IBC# 04-05-019-BL2; PI: [REDACTED]; **TITLE:** Molecular Mechanisms of HIV-Mediated Encephalopathy. The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Request for Change as submitted requesting reclassification from BL3 to BL2. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-05-020-BL2; PI: [REDACTED]; **TITLE:** Neural Immunity in HIV Dementia. The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Request for Change as submitted requesting reclassification from BL3 to BL2. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-05-021-BL2; PI: [REDACTED]; **TITLE:** Training Program in Neurovirology. The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Request for Change as submitted requesting reclassification from BL3 to BL2. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-05-027-BL2; PI: [REDACTED]; **TITLE:** Targeted neuroprotection for HIV-1 associated neurologic disease. The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Request for Change as submitted requesting reclassification from BL3 to BL2. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-05-028-BL2; PI: [REDACTED]; **TITLE:** Immunopathogenesis of HIV Neurological Disorders: Project 2: Monocyte Immunity and HIV-1 Induced Dementia. The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Request for Change as submitted requesting reclassification from BL3 to BL2. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-05-030-BL2; PI: [REDACTED]; **TITLE:** Molecular Mechanisms of HIV Neuropathogenesis. The IBC voted (9 in favor, 0 against, 1 abstention) to approve the Request for Change as submitted requesting reclassification from BL3 to BL2. A letter will be sent to the PI and reflected in Addendum I to the minutes. All IBC members listed as present voted.

D. IBC Continuing Review of BL1 Active Research by Expedited Review

The IBC members were notified regarding expedited review of requests to continue research designated BL-1. The approval verifies that this research continues to satisfy all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 03-08-017-BL1; PI: [REDACTED]; **TITLE:** 1) Role of endocytic recycling regulatory proteins and their impact on cholesterol trafficking. 2) Deciphering the roles of endocytic recycling regulatory proteins and their chronology of action. 3) Integrating molecular mechanisms of endocytic recycling. 4) Impact of endocytic recycling on EGF receptor function.

IBC# 03-12-031-BL1; PI: [REDACTED]; **TITLE:** 1. Ets proteins and TGF-b-receptor gene expression. 2. Elf-3 autoinhibition and TGF-b-receptor gene expression. 3. Regulation of Elf-3 expression. 4. Elf-3 autoinhibition and TGF-b-receptor expression

IBC# 04-01-002-BL1; PI: [REDACTED]; **TITLE:** 1) Mechanisms of gap junction regulation. 2) Mechanisms of control of cell growth by gap junctions.

E. IBC Continuing Review of Active Research

None

IBC MINUTES
December 10, 2004
Page 3

F. IBC Research Proposals Reviewed by Expedited Review

The IBC members were notified regarding an application for initial expedited review that was approved.

IBC# 04-11-048-BL2; **PI:** ; **TITLE:** Biosafety training access for Orthopaedic Research personnel. **Rationale for Expedited Review:** Training access only.
Recommendation by Board: A letter to the PI will be sent to recommend developing generic protocols which would be tied to the biosafety level training needed for the individual and no longer specifically to individual departments.

G. IBC Review of 5-year Rewrites by Expedited Review

IBC members were notified regarding application for expedited review of 5-year rewrites and re-approval set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 04-12-051-ABL1; **PI:** ; **TITLE:** Gene and protein therapy for poisoning by organophosphorus agents.

H. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

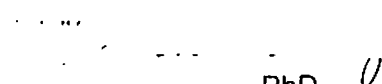
IBC# 04-11-049-BL3; **PI:** **TITLE:** Molecular Genetics of *Mycobacterium tuberculosis*.
The IBC voted (8 in favor, 0 against, 2 abstentions) to conditionally approve the proposal pending receipt of clarifications/documentation for the record in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-11-050-BL3; **PI:** **TITLE:** Propagation and purification of large quantities of HIV-1 in DRC BL3. The IBC voted (9 in favor, 0 against, 1 abstention) to conditionally approve the proposal pending receipt of clarifications/documentation for the record in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-12-052-BL3; **PI:** **TITLE:** Development and validation of diagnostic procedures for the identification of micro-organisms including mycobacteria. The IBC voted (8 in favor, 0 against, 2 abstentions) to conditionally approve the proposal pending receipt of clarifications and/or documentation for the record in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

There being no further business, the meeting adjourned at 4:02 pm.

Respectfully Submitted,


PhD
Chair, IBC

OL/gdk

xc:

14C



NEBRASKA'S HEALTH SCIENCE CENTER

Institutional Biosafety Committee

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
November 12, 2004**

MEMBERS PRESENT: Ursula Lockridge - Chair

(noting)

ALTERNATES NON-VOTING PRESENT: [redacted]

ADMINISTRATIVE STAFF PRESENT: None

Dr. Lockridge opened the meeting at 3:05 pm

A. Review and Acceptance of IBC Minutes

The October 15, 2004 minutes were accepted pending the revision of the correct spelling for

B. Information, Education and Policy Items

Information

[redacted] informed the IBC that a generic IBC Email address has been set up which is entitled: IBCORA.

[redacted] informed the Board that all Laboratory Inspections which have been performed were entered into IBC Database.

A review form for initial submissions was designed by [redacted], secretary for [redacted] and is now being utilized by all IBC Board members assigned as a primary or secondary reviewer.

Email Notifications for Continuing Reviews have been set up and will start being distributed in order for the Board to fulfill its obligation to review protocols annually.

Education

None

Policy

Discussion was held regarding lab inspections being performed prior to approval on BL2 and BL3 protocols. After a lengthy discussion, the board voted 10-0-1 to approve the policy that BL2 protocols may be approved without lab inspections being performed and if following inspection a concern is determined, the PI will be notified by letter which may involve holding up the research. The Board voted 10-0-1 that all BL3 protocols must have the lab inspections performed prior to granting IBC approval.

The IBC discussed the biosafety level assignment of the 6 protocols recently submitted for HIV work in the laboratories of [redacted]. The protocols were designated Biosafety level 3. However, the room in the DRC where this work is conducted has not yet been commissioned. In the Board's discussion it became clear that people who work with small volumes of HIV use BL3 practices even though the NIH Guidelines only require BL2 safety practices, and that they do their HIV work in the room that will in the near future be commissioned as the BL3 facility. The IBC felt that using BL3 safety practices was laudable and urged continuance of this cautious approach for work with HIV. However, the IBC suggested that the biosafety level for the 6 protocols be changed to BL2. The Board voted 9-0-2 to conditionally approve these studies for BL2 pending re-review by the IBC Chair and the Board to make certain the members of the committee also agree that the work in these protocols conforms to NIH Guidelines for biosafety level 2.

The IBC is also requesting that [redacted] submit a new protocol that describes the preparation and purification of large quantities of HIV. This protocol would be designated BL3.

C. IBC Continuing Review of Active Research

The IBC administrative staff performed a pre-review of the applications for continuing review listed below. Any identified errors, deficiencies or other problems were either noted and provided to the primary reviewer or corrected during pre-review. The IBC reviewed the applications for continuing review listed below.

All IBC members listed as present voted on the actions indicated below with the exception of those members listed as absent from the room at the time of the vote or excluded from the vote.

Re-approval and Full Release. *No modifications or clarifications are required. The study is re-approved and released.*

<u>IBC #</u>	<u>PI</u>	<u>Vote Count</u>	<u>Excluded/Absent</u>
03-11-029-BL2	[redacted]	10-0-1	

Conditional Approval. *Minor clarification(s)/revision of the protocol or IBC training requirements which must be completed. A letter detailing the specific points will be sent to the PI and reflected in Addendum I to the minutes.*

<u>IBC #</u>	<u>PI</u>	<u>Vote Count</u>	<u>Excluded/Absent</u>
02-11-032 BL2	[redacted]	10-0-1	

D. IBC Research Proposals Reviewed by Expedited Review

<u>IBC #</u>	<u>PI</u>
04-10-046-ABL1	[redacted]

E. IBC Initial Review of Research Proposals

The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth in the NIH Guidelines for Recombinant DNA and Gene Transfer.

IBC# 04-10-044-BL2: Regulation in HIV-1 associated dementia: [redacted] J, PhD; Pathology; UNMC. The IBC voted (10 in favor, 0 against, 1 abstention) to conditionally approve the proposal pending receipt of clarifications/documentation for the record in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address

IBC MINUTES

November 12, 2004

Page 3

will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-10-045-BL1: A phase I/II study of an anti-tumor vaccination using a(1,3)galactosyltransferase expressing allogeneic tumor cells in patients with hormone refractory prostate cancer (IRB/SRC); [redacted] Urologic Surgery; UNMC. The IBC voted (10 in favor, 0 against, 1 abstention) to conditionally approve the proposal pending receipt of clarifications/documentation for the record in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

IBC# 04-11-047-BL2: Armed Forces Institute of Pathology critical reagent genomic repository program; [redacted] PhD; Pathology; UNMC. The IBC voted (9 in favor, 0 against, 2 abstention) to conditionally approve the proposal pending receipt of clarifications/documentation for the record in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

There being no further business before the Board,
pm.

adjourned the meeting at 4:11

Respectfully Submitted,

Chair, IBC

OL/gdk

xc:

PhD

hD

MD, UNMC

PhD

PhD, UNMC



NOV 17 2004

NEBRASKA'S HEALTH SCIENCE CENTER

Institutional Biosafety Committee

**INSTITUTIONAL BIOSAFETY COMMITTEE
MEETING MINUTES
October 15, 2004**

MEMBERS PRESENT: _____

Dr.
omero,
id DIII

ALTERNATES NON-VOTING PRESENT: _____

ADMINISTRATIVE STAFF PRESENT: None

opened the meeting at 2:35 pm

A. Review and Acceptance of IRB Minutes
No previous written minutes.

B. Information, Education and Policy Items
Information

_____ notified the Board regarding the NIH mandate that the IBC must have convened meetings. The NIH Guidance documents had been previously distributed to all members. The Board understood their responsibility and decided that the second Friday of each month would be the date of the IBC Meetings.

Each Board member was also asked that they appoint an alternate who would attend the IBC meeting when the member was unable to attend.

_____ informed the Board that two reviewers would be assigned to present reviews orally on new submissions. Written reviews are also requested from Board members for protocols in which they are assigned as a reviewer.

The Board was also notified that minutes of each meeting will be recorded and presented at the following meeting for acceptance.

Education
None

Policy
None

Page 2 of 2
10/15/04 Minutes - IBC

C. IBC Initial Review of Research Proposals:

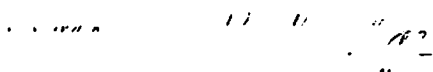
The IBC reviewed the research proposals listed below in order to ensure the research satisfies all the criteria set forth

04-09-041-BL2: A phase III randomized, open-label study of CG1940 and CG8711 versus docetaxel and prednisone in patients with metastatic hormone-refractory prostate cancer who are chemotherapy-naïve; MD; Internal Medicine - Oncology/Hematology; UNMC. The IBC voted (10 in favor, 0 against, 1 abstention) to conditionally approve the proposal pending receipt of clarifications/documentation for the record in response to the Board's review. A letter detailing the specific points that the IBC asked the PI to address will be sent and reflected in Addendum I to the minutes. All IBC members listed as present voted.

There being no further business before the Board
pm.

e adjourned the meeting at 3:25

Respectfully Submitted,


e, PhD

Chair, IBC

OL/gdk

xc: hD
MD, UNMC
iD
t, PhD, UNMC