



OFFICE OF THE VICE PRESIDENT
FOR RESEARCH

201 Gilmore Hall
Iowa City, Iowa 52242-1320
319-335-2119 Fax 319-335-2104

May 2, 2006

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

Dear Mr. Hammond:

Enclosed please find copies of the University of Iowa Institutional Biosafety Committee minutes, as requested.

Sincerely,

A handwritten signature in blue ink, appearing to read "David L. Wynes".

David L. Wynes, Ph.D.
Associate Vice President for Research

cc: Grainne Martin, Senior Associate Counsel
Carol McGhan, Biosafety Officer

the sunshine project

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15 March 2006

Carol Mcghan
University of Iowa
201 Gilmore Hall
Iowa City IA 52242-1320

By fax: (319) 335-2104

Dear Carol Mcghan

Pursuant to the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section IV-B-2-a-(7),¹⁷⁰ the Sunshine Project hereby requests the Minutes of all meetings of the University of Iowa Institutional Biosafety Committee (IBC) since 1 May 2003.

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

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

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

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

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

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

Sincerely,



Edward H. Hammond
Director

¹⁷⁰ Section IV-B-2-a-(7). Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes...



Health Protection Office
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December 10, 2003

To: Institutional Biosafety Committee (rDNA) Members

Subject: Minutes of the Institutional Biosafety Committee (rDNA Committee) meeting of November 11, 2003

Members Present: Dr. Louis Kirchhoff, Dr. Jeffery Meier, Dr. Aloysius Klingelhutz, Dr. Michael Parker, and Ex-officio members Dr. David Wynes and Ms. Carol McGhan

Members Absent: Mr. Douglas Herman, Dr. Keith Hench

Guests Present: Ms. Marilyn Rosenquist, Ms. Deborah Kratz (HPO) and Grainne Martin, J.D.

The meeting was called to order at approximately 3:50 p.m.

Business Agenda:

1. Review and discussion of a gene therapy proposal submitted by Badrinath Konety, M.D., et al. entitled "A phase I study of Ad5-TRAIL in men with clinically organ confined prostate cancer undergoing radical prostatectomy."

The discussion related primarily to the safety of the advenoviral construct to the patient and healthcare workers. The protocol has been reviewed by the NIH OBA and was not selected for in-depth RAC review and public discussion. At the time of this meeting, the protocol had not undergone IRB review.

The protocol was unanimously approved.

2. Development of an electronic rDNA Registration Document.

Ms. McGhan provided copies of the latest electronic version of the rDNA Registration Document for committee members' review. Members provided suggestions for wording changes and a suggestion to have the document automatically populated with the PIs information (name, department and phone number) through the use of the Hawk ID.

The meeting adjourned at approximately 4:45 p.m.

Submitted by: Carol McGhan, CBSP

Approved by: Louis V Kirchhoff, M.D., M.P.H.

Enclosures: Draft electronic rDNA Registration Document
(to Dr. Keith Hench and Douglas Herman)



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March 28, 2004

To: Institutional Biosafety Committee (rDNA) Members

Subject: Minutes of the Institutional Biosafety Committee (IBC; rDNA Committee)
Meeting of February 11, 2004

Members Present: Drs. Louis V Kirchhoff, Jeffery Meier, Michael Parker, Aloysius Klingelhutz,
and Ex-officio members Dr. David Wynes and Ms. Carol McGhan

Members Absent: Mr. Douglas Herman and Dr. Keith Hench

Guests Present: Ms. Grainne Martin, Ms. Deborah Kratz, and Ms. Marilyn Rosenquist

The meeting was called to order at 4:10 p.m.

Business Agenda:

1. Dual-use Issues

Dual-use issues related to biosafety and ethical aspects of protocols proposed by Drs. Steven Varga and Stanley Perlman were discussed at length. Documents that were reviewed and discussed included the "1972 Bioweapon Convention" promulgated by the United Nations, and an article entitled "Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma (2003)" that was issued by a committee of the U.S. National Academy of Sciences.

2. The IBC's Role

Dr. David Wynes and Ms. Grainne Martin discussed the IBC's role in dealing with these complex dual-use issues. Ms. Martin pointed out that since the dual-use issues are not covered specifically by the *NIH Guidelines*, it might be appropriate for them to be considered at a higher administrative level. Dr. Kirchhoff concurred with their view that decisions regarding dual-use should be made at a higher institutional level, or by the Recombinant DNA Advisory Committee (RAC) which is part of NIH's Office of Biotechnology Activities (OBA). At this point, since several committee members have reached out to OBA for guidance and have not received any to date, it was agreed that the proper route for addressing these issues would be through an ad hoc committee convened by the Office of the Vice President for Research (VPR). To that end, a plan was agreed upon in which Dr. Kirchhoff will write a letter to VPR Dr. William Decker addressing the following topics:

- (1) Background information relating to ethical issues raised by dual-use research;
- (2) a description of the experiments of concern proposed by Drs. Varga and Perlman; and

(3) a suggestion would be made to assemble a diverse group to decide if approval of such experiments of concern will be granted at the University of Iowa.

3. Dr. Stanley Perlman's Registration Documents

Specific actions taken by the IBC on Dr. Perlman's pending registration documents were to request he submit a new rDNA document for the part of his proposal that involves the use of the plasmid pBluescript at BSL2, since this work could be approved by the IBC. The remainder of Dr. Perlman's proposed work was not approved and will be addressed in the review by the VPR's Office.

4. Dr. Steve Varga's Registration Document

Due to the issues previously mentioned, Dr. Varga's protocol was not approved. In an effort to identify experiments from this document that would be approvable and not be held up due to the proposed review in the Office of the VPR, Dr. Jeffery Meier will work with Dr. Varga. They will identify experiments, such as those involving the insertion of a variety of genes in attenuated viral vectors, and submit for the Committee's review a new rDNA Registration Document describing these experiments. Also, Dr. Parker suggested that instead of using human viruses, Dr. Varga should look into whether substituting a couple of mouse viruses, such as Sendai or Pneumonia Virus of Mice (PVM), might yield the desired result and minimize or eliminate the Committee's concerns with the organisms in the current proposal. The experiments not included in this new proposal will be addressed in the review by the Office of the VPR.

The meeting adjourned at approximately 6:30 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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September 9, 2004

To: Institutional Biosafety Committee (rDNA) Members

Subject: Minutes of the Institutional Biosafety Committee (IBC; rDNA Committee)
Meeting of September 9, 2004

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, Aloysius Klingelhutz,
and Ex-officio members Dr. David Wynes and Ms. Carol McGhan

Members Absent: Mr. Douglas Herman

Guests Present: Ms. Deborah Kratz, and Ms. Marilyn Rosenquist

The meeting was called to order at 4:10 p.m.

Business Agenda:

1. **Approval of minutes from February 11, 2004 meeting.**
Dr. Parker made a motion, seconded by Dr. Klingelhutz, to approve the minutes of the last meeting.
2. **Experiments of Concern**
Dr. Kirchhoff, Ms McGhan, Dr. Wynes and Mr. Bill Decker met in April to discuss how the University will review future protocols that are determined to be “experiments of concern” i.e., meet criteria listed in the National Academy of Sciences’ 2003 report on dual use issues. Since Drs. Steven Varga and Stanley Perlman resubmitted protocols which did not include work involving issues that previously concerned the committee, no such protocols are currently in need of review. However, the VPR’s Research Council might be the local group called upon to review these, unless the NIH’s Office of Biotechnology Activities or the National Science Advisory Board for Biosecurity, established to develop guidelines at a national level, assume the responsibility for reviewing protocols that involve experiments of concern.
3. **Open Meetings**
Since the IBC is not a charter committee of the University, open meetings rules do not apply. Upon request, minutes of the IBC’s meetings are made available to the public. If someone makes a request to attend an IBC meeting, he/she would be referred to Dr. Wynes.
4. **Evaluation of complex protocol procedures**

In the review of protocols that involve complex issues, Dr. Kirchhoff suggested the committee use the following procedures:

- PIs will be requested to re-write their protocols.
- If additional information is required, committee members and the PI should meet formally, so all members can be involved.
- When using a non-IBC expert, the consultation will be done in confidence and they will be asked to provide an opinion to the IBC only. The IBC will formally meet to discuss the issues and opinions to eliminate any pressures on the consultants or individual committee members.

5. Unanimous Votes on Protocols

A question was asked regarding whether protocols must have unanimous approval, and if there is a dissenting vote, how that should be handled. It was agreed that when questions are raised by committee members,

- Biosafety staff will continue to request additional information from the PI;
- all safety issues must be addressed; however,
- if a committee member does not want to give a vote of approval, the biosafety staff are to remind the member that a meeting can be called and is recommended if more information and agreement can be gained by doing so.

6. Member retired

Keith Hench resigned as a community member, since his spouse now works for the University. The *NIH Guidelines* specifically prohibit a community member from also having an affiliation with the institution, which includes the spouse, partner or child. Members are encouraged to offer names of individuals to serve as a community member on our committee.

7. NIH Conference

Ms. McGhan informed the committee that a Web cast of an NIH Safety Symposium will be available September 21-22; if anyone is interested in listening to it, the website is:
<http://www4.od.nih.gov/oba/rac/Sept2004/safetysymp.htm>

The meeting adjourned at 4:55 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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April 25, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of March 23, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, Aloysius Klingelutz; Mr. Douglas Herman, Mr. Shawn Walsh, and Ex-officio members Dr. David Wynes and Ms. Carol McGhan

Guests Present: Ms. Deborah Kratz

The meeting was called to order by Dr. Kirchhoff at 3:50 p.m.

Business Agenda:

1. **Approval of minutes from September 9, 2004 meeting:**
 Dr. Meier made a motion, seconded by Dr. Parker, to approve the minutes of the September 9, 2004, meeting. The members voted unanimously to approve the minutes.
2. **Introduction of new IBC member:**
 Shawn Walsh, a new IBC member, was introduced. Mr. Walsh is employed at Integrated DNA Technologies, Inc. and became a member of the IBC in November 2004.
3. **Protocols under review:**
 The following three protocols were discussed:

rDNA#	PI	rDNA Registration Document Title
05027	Jones, Bradley	Capsule gene mutations in <i>Francisella</i> strains
05028	Apicella, Michael	Studies of the LPS and Capsular Antigen of <i>F. tularensis</i>
05042	Apicella, Michael	Studies of the LPS and Capsular Antigen of <i>F. tularensis</i>

Dr. Kirchhoff reviewed the issues relating to the insertion of antibiotic genes that was included in each of the three protocols. CDC had previously provided the University with a memo stating which antibiotic resistance markers would be acceptable for use in the specific select agent under discussion and additional reference materials were also reviewed. Dr. Meier made a motion, seconded by Dr. Klingelutz, that all three protocols be approved. The committee unanimously approved the three protocols.

Ms. McGhan stated that she will check with the other investigators listed on two of the protocols to determine what work will be done in their laboratories as part of the project. In relation to this discussion, it was also decided that HPO should inspect laboratories leased by the VAMC at the MTF, as many of these are space shared with UI investigators.

4. **IBC Standard Operating Procedure (SOP)**
 The IBC's SOP was recently revised extensively to include the process for expedited review of rDNA protocols that do not meet the criteria for convening an IBC meeting. At a national level, the issue of

IBC meetings is being discussed and Dr. Wynes presented the revised IBC SOP for consideration at a recent meeting of the Council on Governmental Regulations (COGR). IBC members were asked to offer suggestions for any changes they would like to see incorporated into the revised SOP and the rDNA Registration Document.

5. List of protocols approved through expedited process:

The list of protocols that have been approved through the expedited review process since the September IBC meeting was distributed. Dr. Meier made a motion, seconded by Mr. Walsh, that the list of protocols be approved and incorporated into the meeting minutes. The motion passed unanimously.

6. UIRIS Routing Form:

Ms. McGhan presented a request made by a principal investigator (PI). On the current UIRIS Routing Form, a PI can check a box indicating that the research in the proposed project involving rDNA is exempt from the *NIH Guidelines*. Doing so results in a memo being sent from the Division of Sponsored Programs to the PI requesting that the basis for the exemption be explained. Such explanations subsequently are reviewed by IBC staff. The PI who had contacted Ms. McGhan regarding the UIRIS Routing Form requested that a space be provided therein for explaining the basis for the exemption from the *NIH Guidelines*. After discussion, the committee rejected that request, as it was decided that the UIRIS Routing Form was not the appropriate document for providing a detailed explanation for the basis of the exemption.

7. Recent Violations of the *NIH Guidelines* reported to the Office of Biotechnology Activities at NIH (NIH/OBA).

Dr. Kirchhoff described two violations of the *NIH Guidelines* that occurred recently at the University and reviewed the manner in which the violations were processed and reported to NIH/OBA. The *NIH Guidelines* do not contain specific administrative procedures for reporting violations beyond indicating that they must be reported either by the institution or the violators. Likewise the IBC SOP current at the time the violations occurred, as well as the revised version prepared subsequently, do not contain specific guidance in this regard. The recent violations were discussed at some length and no proposal was made to revise the IBC SOP as it relates to the handling of violations. It was generally agreed that violators should be asked to provide technical descriptions of their violations, as well as outlines of their plans for preventing recurrence of violations of the *NIH Guidelines*. This technical information and the preventive plans then would be incorporated into the violations letters being sent to NIH/OBA. It was also generally agreed that violators should be informed that the violations will be reported to NIH/OBA as required under the *NIH Guidelines*. Committee members generally felt that copies of violations letters be provided to violators only after they are mailed to NIH/OBA.

The meeting adjourned at 5:35 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee

Attachment: Expedited Review rDNA Registration Documents Sept 2004 – March 23, 2005



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June 14, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of June 6, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, Aloysius Klingelhutz; and Ex-officio member Ms. Carol McGhan

Guest Present: Dr. Haley Sinn

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:30 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda:

1. **Approval of minutes from March 23, 2005 meeting:**
Dr. Klingelhutz made a motion, seconded by Dr. Meier, to approve the minutes of the March 23, 2005, meeting. The members voted unanimously to approve the minutes.
2. **Introduction of new biosafety staff member:**
Dr. Haley Sinn, the new Associate Biosafety Officer, was introduced.
3. **Protocols under review:**
The following five protocols were discussed and approved:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05074	Beverly Davidson	Broad Approval for FIV Vector Construction and amplification for non-UI investigators at the Gene Transfer Vector Core

The discussion included confirming that this broad approval was for work that did not involve the insertion of oncogenes.

Record of voting: Dr. Klingelhutz- approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05075	Beverly Davidson	Broad Approval for AAV Vector Construction and amplification for non-UI investigators at the Gene Transfer Vector Core

The discussion again involved noting that this broad approval was for work that did not involve the insertion of oncogenes.

Record of voting: Dr. Klingelhutz- approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

These broad approvals will involve the quarterly submission of a table listing the virus name, investigator, institution and gene name. The information can be submitted on the same table that is currently submitted on a quarterly basis for work that involves replication-deficient adenovirus vectors created for non-UI investigators under a broad approval.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05076	Beverly Davidson	GTVC-FIV Vector Construction

This was for the construction of an FIV vector for a non-UI investigator and no genes are expressed by this construct in Dr. Davidson's laboratory.

Record of voting: Dr. Klingelhutz- approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05077	Beverly Davidson	GTVC-FIV Vector Construction

This was for the construction of another FIV vector for a non-UI investigator and no genes are expressed by this construct in Dr. Davidson's laboratory.

Record of voting: Dr. Klingelhutz- approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05078	Beverly Davidson	Virus Production and Amplification non-UI Investigators 1 st Qt 2005

This is Dr. Davidson's quarterly report for adenovirus constructs and listed only one construct.

Record of voting: Dr. Klingelhutz- approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

4. IBC Basics Course

Dr. Kirchhoff announced that a course on "IBC Basics" instructed by Dr. Kathryn Harris and Allan Shipp, both from NIH/OBA, will be offered on August 1st at a Midwest Area Biosafety Network meeting (MABioN) in Indianapolis, IN. Dr. James Walker, Director, HPO, has offered to cover the expenses (registration, conference hotel, and travel) of IBC members who attend. Ms McGhan will send additional information by E-mail to members in the near future.

5. NIH Response to Violations

Dr. Klingelhutz inquired whether NIH/OBA had responded to Dr. Kirchhoff's March 11, 2005 report of violations of the *NIH Guidelines*. Dr. Kirchhoff informed the members that a favorable response was received and copies of the letter will be sent to all members.

The meeting adjourned at 3:50 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: June 21, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of June 20, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, Aloysius Klingelhutz; and Ex-officio member Ms. Carol McGhan

Members Absent: Mr. Douglas Herman, Mr. Shawn Walsh, ex-officio member Dr. David Wynes

Guest Present: Dr. Haley Sinn, Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda:

1. **Approval of minutes from June 6, 2005 meeting:**
 Dr. Klingelhutz made a motion, seconded by Dr. Meier, to approve the minutes of the June 6, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Next IBC meeting:**
 As the next scheduled meeting would fall on July 4th, it was agreed that the next meeting would be moved to July 5th at 3:30 p.m.
3. **IBC Basics course:**
 Dr. Kirchhoff asked if anyone was planning on attending the IBC Basics course being offered in Indianapolis on August 1st. No one planned on attending, at this time; however, Dr. Kirchhoff indicated he might be able to attend.
4. **Protocols under review:**
 The following eight protocols were discussed:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05079	Eric Dickson	Effect of Met-Enkephalins in Ischemic tolerance

There was discussion about changing the animal biosafety level to ABSL2d for work in rabbits and notifying the PI that he needs to contact the Office of Animal Research (OAR) regarding this issue. With that change incorporated into the rDNA Registration Document, the record of voting is: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05081	Hasimu Hapahake	Regulation of TRAF2 Activity in normal and tumor cells

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05082	Jacob Ijdo	Tyrosine phosphorylation during A. phagocytophilum invasion

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05083	Jim Jung-Ching Lin	Control of cardiac troponin T gene expression

Discussion involved the list of target vectors and whether they present any concerns for the committee. Dr. Sinn stated that she is familiar with the vectors and they are neutral and do not present a risk.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05084	Larry Oberley	Get immortalization in Human Skin Fibroblasts

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05085	Larry Oberley	Antitumor Therapies Based on Antioxidant Enzyme Modulations

As the list of target vectors includes plasmids that are not described, a vote on the protocol was placed on hold until specific information is provided on the plasmids to be used in this project.

rDNA#	PI	rDNA Registration Document Title
05087	Richard Smith	Non-Syndromic hearing loss- a collaborative study

As the vectors are listed as “variety of plasmids” and are not described, a vote on the protocol was placed on hold until specific information is provided on the vectors/plasmids to be used in this project.

rDNA#	PI	rDNA Registration Document Title
05088	Steve Varga	Pathogenesis of SARS-CoV

Discussion included the following issues: where the work would be done, since the CBRB’s BSL3 facility will not be completed for several months; the issue of dual use was raised; additional information is needed regarding the attenuation of the RSV deltaSH strain that the PI proposes to use; effective drugs for treating RSV infections are not currently available; there was a suggestion that virologists who are not members of the IBC be consulted regarding the appropriateness of using the RSV deltaSH strain to express SARS-CoV genes individually; a suggestion was made to have the PI provide the IBC with his rationale for using this virus; and a request was made to have the PI explain why he needs to use of animals for this work, especially in light of his having approval to do similar experiments in animals using an attenuated influenza virus into which SARS-CoV had been inserted individually.



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It was decided that Dr. Kirchhoff and Ms. McGhan will generate a list questions to which Dr. Varga will need to respond. The possibility of meeting with Dr. Varga was discussed and it was decided to reconsider this issue after he has responded to the questions that will be sent to him and after contacts have been made with the consultants and clinical staff.

5. Old Business

Dr. Klingelhutz inquired about follow-up to the NIH/OBA letter in response to the reported violations in which it was recommended that the UI review its training programs relevant to the *NIH Guidelines* to ensure investigators are informed of the requirements. Ms. McGhan responded that the biosafety staff will create a PowerPoint course that will be placed on HPO's website, after IBC members' have reviewed and commented on it. Assistance from the IBC regarding the process of educating the investigators on the *NIH Guidelines* and the UI rDNA requirements will be needed.

6. New Business - none

The meeting adjourned at 4:40 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: July 6, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 5, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, and Ex-officio member Ms. Carol McGhan

Members Absent: Mr. Shawn Walsh, Mr. Douglas Herman, Dr. Aloysius Klingelutz and ex-officio member Dr. David Wynes

Guests Present: Dr. Haley Sinn, Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:30 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda:

1. **Approval of minutes from June 20, 2005, meeting:**
 Dr. Meier made a motion, seconded by Dr. Parker, to approve the minutes of the June 20, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following fourteen protocols were discussed:

rDNA#	PI	rDNA Registration Document Title
05085	Larry Oberley	Antitumor Therapies Based on Antioxidant Enzyme Modulation

Dr. Parker requested that the rDNA Registration Document reflect that plasmids introduced into mice would be listed as ABSL1. With that change incorporated into the document, the record of voting is: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05086	Richard JH Smith	Using RNAi to reverse the deafness phenotype in mice

Dr. Parker requested that a change be made to the rDNA Registration Document used by all PIs to include a separate column for animal biosafety levels in the table. As the members present agreed with this suggestion, Ms. McGhan will update the online form to accommodate the request. Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05087	Richard Smith	Non-syndromic hearing loss – a collaborative study

There was discussion regarding the plasmids used in this protocol. It was decided that the plasmids are not a substantive concern.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05089	Jackie Bickenbach	Dedifferentiation of Skin Keratinocytes

It was noted that a committee member had inquired about the deletions listed on the rDNA Registration Document relative to the replication deficient adenoviral construct. The rDNA document will be corrected to reflect that the adenovirus has an E1/E3 deletion.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05090	Charles Yeaman	Role of Protein Kinase D in polarized membrane trafficking

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05092	Mark Stinski	Regulation of Human Cytomegalovirus Gene Expression

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05093	Richard Smith	A Collaborative Study of Membranoproliferative Glomerulonephritis Type II

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05094	Toshiki Itoh	Analysis of DDB-mediated Signaling Pathway in Human Disease and Cancer

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05095	Stanley Perlman	Pathogenesis of MHV-induced demyelination in RAG1 ^{-/-} mice

Discussion involved the MHV strain that would be used. It was agreed to vote on the protocol under the assumption that the strain used in this protocol is confirmed to be an attenuated neurotropic strain. If it is found to be something different, the protocol will be brought back to the committee for further discussion.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05096	Michael Welsh	Welsh lab Recombinant DNA used in cell lines

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05097	Michael Welsh	Welsh lab Recombinant DNA used in animals

Discussion involved the fact that most of the listed ACURF protocols have expired. It was agreed that the vote of approval would be contingent upon Dr. Welsh's submission of updated information



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that includes the appropriate listing of currently approved ACURFs.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05098	Michael Welsh	Welsh lab Recombinant DNA used in transgenics

Discussion included the fact that again, most of the listed ACURF numbers have expired. It was agreed that the vote of approval would be contingent upon Dr. Welsh's submission of updated information that includes the appropriate listing of currently approved ACURFs. Additionally, Dr. Parker pointed out that it would be difficult for the Office of Animal Resources (OAR) to meet Dr. Welsh's needs in the creation of transgenic pigs. In any event, however, the issue would have to be resolved between OAR and Dr. Welsh.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05099	Douglas Trask	Genetically Targeted Radiotherapy of Head & Neck Cancer: Preclinical Biodistribution and Toxicity analysis

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05100	Douglas Trask	A Preclinical Toxicity Analysis for Genetically Targeted Radiotherapy in Head & Neck Cancer:

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

3. Old Business

There was discussion about the draft memo to Dr. Steve Varga written by Dr. Kirchhoff relative to last meeting's decision to table Dr. Varga's rDNA Registration Document pending his responses to additional questions from the IBC. It was decided that Dr. Kirchhoff would consolidate some of the questions. Once the committee reviews Dr. Varga's responses, UI virologists who are not members of the committee may be consulted.

4. New Business – the next IBC meeting will be July 18th at 3:30 pm.

5. Point of order

The question of whether the IBC could vote on rDNARDs when no non-University member is present was raised. It was decided that Dr. Wynes will need to be consulted regarding this issue.

The meeting adjourned at 4:20 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: July 19, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of July 18, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, and Ex-officio member Ms. Carol McGhan

Members Absent: Mr. Douglas Herman, Dr. Aloysius Klingelhutz and ex-officio member Dr. David Wynes

Guests Present: Dr. Haley Sinn, Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Meier at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda:

1. Protocols under review:

The following protocol was discussed prior to Dr. Kirchhoff joining the meeting:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05105	Louis V Kirchhoff	Recombinant Assays for Chagas Disease

There were no issues for discussion pertaining to the protocol.
Record of voting: Dr. Meier – approved; Dr. Parker – approved.

Dr. Kirchhoff joined the meeting and the following three protocols were discussed:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05102	Todd Fairchild	Bifidobacterium as an anti-cancer vector directed against Swarm rat chondrosarcoma

The issue of whether the bedding and cages should be autoclaved prior to disposal was raised due to the use of a vector containing a gene that encodes resistance to spectinomycin. In this application, although not clinically relevant, there was concern about introducing this antibiotic resistance gene into the environment. Dr. Kirchhoff will check into this further. If it is not a problem, the rDNA registration document will be left as ABSL1; however, if it is advisable to autoclave the bedding and cages, it will be changed to ABSL2c on the document before it's approved. With that contingency, the voting proceeded as follows:

Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05103	Jackie Bickenbach	The role of Oct-4 in skin keratinocyte multipotency

It was noted that the rDNA registration document indicated an animal biosafety level (ABL1), even though no animals are used in this protocol. The document will be corrected.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05104	Marc Wold	Functional Roles of Cellular Proteins in DNA Replication

There was discussion regarding the plasmids used in this protocol. It was decided that the plasmids are not a substantive concern.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

2. Approval of minutes from July 5, 2005, meeting:

Dr. Meier made a motion, seconded by Dr. Parker, to approve the minutes of the July 5, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.

3. Old Business

Dr. Kirchhoff reported that he had sent Dr. Varga additional questions, as discussed during the last IBC meeting, relative to his pending rDNA Registration Document involving the insertion of SARS-CoV genes into RSV. Dr. Kirchhoff also indicated that he had discussed with Dr. Varga the need to have the responses in writing.

4. New Business – the next IBC meeting will be August 3rd at 4:15 pm.

The meeting adjourned at 3:55 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee.



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Date: August 11, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 3, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, Aloysius Klingelhutz; and Ex-officio member Ms. Carol McGhan

Members Absent: Mr. Douglas Herman, ex-officio member Dr. David Wynes

Guest Present: Dr. Haley Sinn

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 4:17 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda:

1. **Approval of minutes from July 18, 2005 meeting:**
Dr. Parker made a motion, seconded by Dr. Klingelhutz, to approve the minutes of the July 18, 2005, meeting, which had been sent to committee members. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **New IBC members:**
Dr. Kirchhoff reported that Dr. Wynes has suggested that Ms McGhan and Dr. Sinn be made full IBC members. Dr. Kirchhoff will give his approval of these appointments to Dr. Wynes.
3. **Status of Dr. Steve Varga's rDNA Registration Document Review**
Dr. Varga has responded to the questions posed to him by the committee; however, Dr. Kirchhoff noted that at least one question was not answered. Dr. Kirchhoff will request the additional information from Dr. Varga and provide his response to the committee for review. Dr. Kirchhoff will also contact Dr. Katherine Harris at OBA for her counsel regarding the "experiments of concern" in Dr. Varga's proposed research. Dr. Klingelhutz commented that he is in agreement with this approach.
4. **Recent Activities relating to IBC Functions and Procedures**
Dr. Kirchhoff apprised the IBC members of recent interactions between Dr. Wynes and OBA staff regarding the format for IBC meetings, in addition to requirements for information reviewed during IBC meetings and documented in the IBC's meeting minutes. Ms McGhan briefly commented on a recent meeting entitled "IBC Basics" that was held in Indianapolis at

which Alan Shipp and Dr. Kathryn Harris from OBA gave presentations. Dr. Parker inquired as to whether it is required that a community member be present during a meeting, and Dr. Kirchhoff explained that at the present time there is no specific guidance on this issue.

5. Protocols under review:

The following twenty protocols were discussed:

rDNA#	PI	rDNA Registration Document Title
05080	Robert Felder	Cytokines and Sympathetic Activation in Heart Failure

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05106	Bahri Karacay	Mechanism of maturation-dependent neuroprotection against alcohol

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
5108	David H. Price	Recombinant DNA protocols used in the Price Lab

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05109	Beverly Davidson	Transgene tolerance: a role for apoptosis

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05110	John Lee	Application of Ad:HPV-16 vector to mice to stimulate HPV infection

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Parker inquired as to whether the HPV in mice required ABSL3. The committee had made the determination several years ago that this research required ABSL3 facilities and Dr. Lee has had prior approval to do this research in the VA's BSL3 facility.

Record of voting: Dr. Klingelutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05111	John Colgan	Regulation of Atopic Immune Responses by the Prolyl Isomerase Cyclophilin A

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. A question was raised as to whether the recombinant vector would be put into mice, as the protocol was not clear on this issue. The protocol was voted on with the understanding that this issue would be clarified on the document.

Record of voting: Dr. Klingelutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05112	Al Klingelutz	Studies using hTERT and hTR replication deficient viral vectors

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
5113	Jeff W. Stevens	Transgene Expression of PSACH-linked Mutant Cartilage Oligomeric Matrix Protein

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. There is no record that this PI has prior experience working with rDNA and /or previous approval of an rDNARD; however, since the experiments proposed here require BSL1 practices and facilities, it does not raise a training issue.

Record of voting: Dr. Klingelutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05114	Tim Ratliff	Platelet-mediated modulation of B cell immunity

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05115	Frederick E Domann	Oxidative Events in Cancer Therapy (Project 4)

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05116	Christie P Thomas	Regulation of sFlt1 expression in preeclampsia

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05117	Christie P Thomas	Regulation and function of Nedd4-2 in the collecting duct

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05118	Aliye Uc	Regulation of Heme Uptake and Transport in Caco-2 cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05119	Mary E. Wilson	Interactions of Leishmania chagasi with Host Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05122	John B. Stokes	O'Brien Kidney Research Center

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05123	John B Stokes	O'Brien Kidney Research Center

(haha)

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05124	Patrick Sinn	Targeted Integration of a Lentiviral Vector

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Co-Investigator is Paul McCray who has many years experience working with lentiviral vectors.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05125	Gregory S. Hagemann	Interdisciplinary Programs in AMD (02137)

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Since Dr. Hagemann has not worked with recombinant adenoviruses in the past, the rDNA approval letter will state that the PI must receive training from someone experienced in working with recombinant adenoviruses prior to conducting the work.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05124	Gregory S. Hagemann	Age-related Maculopathy: Cellular and Molecular Analyses (02138)

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. As stated for the protocol listed above, since Dr. Hagemann has not worked with recombinant adenoviruses in the past, the rDNA approval letter will state that the PI must receive training from someone experienced in working with recombinant adenoviruses prior to conducting the work.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

rDNA#	PI	rDNA Registration Document Title
05127	Mario Ascoli	Regulation of follitropin actions

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience.

Record of voting: Dr. Klingelhutz – approved; Dr. Meier – approved; Dr. Parker – approved; Dr. Kirchhoff – approved.

6. **Old Business** – none

7. **New Business** – Next meeting will be August 15, 2005 at 3:30 p.m.

The meeting adjourned at 4:58 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: August 15, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 15, 2005

Members Present: Drs. Louis Kirchhoff, Aloysius Klingelhutz; Ms. Kim Lennox and Carol McGhan

Members Absent: Drs. Jeffery Meier, Michael Parker, Haley Sinn; Mr. Douglas Herman, ex-officio member Dr. David Wynes

Guest Present: Ms Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda:

1. **Approval of minutes from meeting on August 3, 2005:**
Dr.Klingelhutz made a motion, seconded by Ms. McGhan, to approve the minutes of the August 3, 2005, meeting, which had been sent to committee members. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **New IBC members:**
Dr. Kirchhoff welcomed Kim Lennox, a new community member, and Ms. McGhan and Dr. Sinn, who are now full IBC members.
3. **New voting method**
Dr. Kirchhoff stated that he will take a voice vote regarding each rDNA Registration Document being considered, rather than polling members individually.
4. **Protocols for the Inflammation Group**
Biosafety staff has received three rDNA Registration Documents submitted by the Inflammation Group. After initial review it is clear that these submissions have numerous administrative and formatting deficiencies. Dr. Kirchhoff discussed these issues in some detail by telephone with Dr. Nauseef, the head of the Inflammation Group. Dr. Kirchhoff will meet with Dr. Nauseef on Wednesday the 17th to clarify the changes that will be required before the rDNARDs can be sent to committee members for review.

5. IBC rDNA review process change

Dr. Kirchhoff explained that the email sent to committee members prior to each meeting with the rDNA Registration Documents attached will continue to contain a table listing the protocols; however, only members who will not be able to attend the meeting and who have questions or concerns about a particular protocol need to reply to the email. Questions or concerns should be sent to Ms. McGhan or in her absence other biosafety staff, and they will then be read at the meeting. Only members who attend the meeting vote on the rDNA Registration Documents under consideration.

6. Protocols under review:

The following eight protocols were considered:

rDNA#	PI	rDNA Registration Document Title
051210	Jim Lin	Investigating the role of the novel Xin protein at the adherens junction of the intercalated disc in mouse hearts

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 4-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05128	Paul McCray	Filovirus Enveloped FIV: virus-epithelia interactions for CF

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2. A vote was taken with the understanding that the document will reflect a clarification regarding a question on the conferring of resistance and blastacidin.

Vote: 4-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05129	Timothy Yahr	<i>E. coli</i> and <i>Y. pestis</i> type III secretion

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and that it does not involve an agent that is subject to the select agent requirements.

Vote: 4-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05130	Robin Davisson	Oxidant Stress in the Brain and Hypertension

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, with ABSL1 for FIV and ABSL2c for Adenovirus in mice.

Vote: 4-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05131	Val C. Sheffield	Molecular Genetic of Hereditary Glaucoma

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 4-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05132	Beverly Davidson	Use of CLN3 to Generate CLN3 Antibodies

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1 for AAV and FIV in mice and hamsters and ABSL2c for adenovirus research in animals. A vote was taken with the understanding that the document will reflect a clarification of the plasmids that will be used as vectors, as listed in 1f (1).

Vote: 4-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05133	Rama Mallampalli	TNF alpha-lipoprotein control of a surfactant enzyme in sepsis-induced lung injury

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 4-0 for approval.

rDNA#	PI	rDNA Registration Document Title
5134	Craig Morita	Gamma Delta T Cell Recognition in Tularemia

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c. The committee requested that Biosafety staff ensure that Dr. Brad Jones has rDNA approval for the work that he will conduct for Dr. Morita, as identified in this proposal. There was also discussion regarding the pathogenicity of *Salmonella typhi* Ty21a, a vaccine strain.

Vote: 4-0 for approval.

7. **Old Business** – none

8. **New Business** – Next meeting will be August 29, 2005 at 3:30 p.m.

The meeting adjourned at 3:58 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: September 6, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of August 29, 2005

Members Present: Drs. Louis Kirchhoff, Brian Hanzelka, Aloysius Klingelhutz, Jeffery Meier and Haley Sinn; Ms. Kim Lennox and Ms. Carol McGhan

Members Absent: Mr. Douglas Herman and Dr. Michael Parker; ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda:

1. **New IBC member**
Dr. Kirchhoff introduced and welcomed Dr. Brian Hanzelka, a new community member.
2. **Approval of minutes from meeting on August 15, 2005**
Ms. Lennox made a motion, seconded by Dr. Sinn, to approve the minutes of the August 15, 2005, meeting, which had been sent to committee members. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
3. **Status of Dr. Varga's SARS-CoV/RSV rDNARD**
Dr. Kirchhoff provided a brief explanation regarding the background on the rDNA Registration Documents submitted to the IBC by Dr. Steve Varga. In reviewing the most recent submission, the committee had requested more information, and Dr. Kirchhoff has had several communications with Dr. Varga to answer the committee's questions. Dr. Kirchhoff will circulate copies of Dr. Varga's responses and Dr. Kirchhoff's notes from his discussions with him in which he learned that Dr. Varga has not done the previously-approved experiments with SARS-CoV/influenza.

Dr. Kirchhoff will also write OBA to request an opinion on Dr. Varga's latest proposal.
4. **Quarterly Audits of Welsh Laboratory**
In 2001, the IBC reported a violation of the *NIH Guidelines* to NIH/OBA that involved the laboratory of Dr. Michael Welsh. As a consequence of that report, NIH made several recommendations, one of which involved heightened surveillance of Dr. Welsh's rDNA activities

and resulted in HPO Biosafety staff auditing Dr. Welsh's laboratory on a quarterly basis. Dr. Kirchhoff asked committee members for their recommendations regarding the need for the continuation of these audits, since it has been approximately 5 years since they were initiated. Dr. Klingelutz made a motion, which was seconded by Ms. McGhan, to the effect that Dr. Welsh's laboratory undergoes the same annual audits as other principal investigators, and that the quarterly audits are discontinued. IBC members voted unanimously to approve this change in the oversight of Dr. Welsh's laboratory.

5. **Monitoring Program for the laboratories of Drs. Bradley Jones and Michael Apicella**
Dr. Kirchhoff asked committee members for their recommendations regarding heightened surveillance of these two laboratories in view of the IBC's February 2005 report to OBA regarding violations of the *NIH Guidelines*. Committee members did not feel that extra oversight was necessary, as the nature of the violations was different than that of the incident reported in 2001.
6. **Training Materials**
A draft training program has been distributed to members for their review and comments. Members were asked to come to the next meeting prepared to discuss the draft.
7. **Protocols under review:**
The following nine protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05136	Beverly Davidson	The Effects of the Tat-motif on the Intracellular Trafficking of B-Glucorinidase

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 7-0 for approval.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05137	Beverly Davidson	Hereditary Disease Foundation proposal, 2005

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 7-0 for approval.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05138	Beverly Davidson	The analysis of a CLN3 reporter mouse

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee requested that the proposal be reconsidered after there is a clear understanding about what previous work with transgenic mice has been done and what the proposed work entails.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05142	Larry Oberley	A novel ALS therapy to inhibit mutant SOD1-induced mitochondrial damage and neuron toxicity

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, with ABSL2c for adenovirus work in mice.

Vote: 7-0 for approval.

rDNA#	PI	rDNA Registration Document Title
5143	Kevin Kregel	Oxidative Stress and Aging: Integrated Mechanisms

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 7-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05144	Douglas Trask	Reactive Oxygen Species Inhibition of Oral Cancer Growth

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c for adenovirus research in animals.

Vote: 7-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05145	Milind Deshpande	Growth of Recombinant <i>E. coli</i> Cultures at 100 Liter Scale

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2-LS. A vote was taken with the understanding that Dr. Milind will provide a statement that the synthetic peptides are not related to a toxin or are not directly known to be toxic, either by performing a database search or through a direct assay test.

Vote: 7-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05146	Paul McCray	RNAi Interference of Respiratory Viruses

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. As more information and clarification was needed for this protocol, Dr. Meier agreed to discuss the proposed work with Dr McCray and request that he submit a revised rDNA Registration Document to the committee that clarifies the proposed work.

rDNA#	PI	rDNA Registration Document Title
5147	Christopher Stipp	Transgenic alpha-5 integrin in neuronal regeneration

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABS1.

Vote: 7-0 for approval.

8. **Old Business** – none

9. **New Business** – Next meeting will be September 12, 2005 at 3:30 p.m.

The meeting adjourned at 4:20 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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 Fax 319-335-7564

Date: September 19, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 12, 2005

Members Present: Drs. Louis Kirchhoff, Brian Hanzelka, Aloysius Klingelhutz, Jeffery Meier, Michael Parker and Haley Sinn; Ms. Kim Lennox and Ms. Carol McGhan

Members Absent: Mr. Douglas Herman; ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on September 6, 2005**
 Dr. Meier made a motion, seconded by Dr. Hanzelka, to approve the minutes of the September 6, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following nine protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05138	Beverly Davidson	The analysis of a CLN3 reporter mouse

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1, with ABSL1 for the work in mice.

Dr. Davidson had clarified that the work in the mice had previously been done under an approved protocol, however, the document needed to reflect that this work only involved staining tissues from the mouse. The committee voted on the protocol with the assumption that the table would be corrected to accurately reflect the work being done at this time.
 Vote: 8-0 for approval.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05148	Alexander Horswill	Investigating Quorum Sensing in <i>Staphylococcus aureus</i>

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 8-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05149	Mohammed Filali	Role of CIC-3 in ROS Export and Intracellular signaling in Vascular Smooth Muscle Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 8-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05150	Dwight Look	Epithelial Cell response to <i>H. influenzae</i> in the Airway

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 8-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05151	John Stokes	O'Brien Kidney Research Center

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 8-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05152	Mary Wilson	Interactions between Leishmania and the Immune Response

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, with ABSL2c for the work in mice.

Vote: 8-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05153	Mary Wilson, et al	Collaborative Development of a Vaccine against Cutaneous and Visceral Leishmaniasis

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 8-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05154	Francis Miller	Overexpression of NADPH Oxidase Subunits in Smooth Muscle Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 8-0 for approval.

rDNA#	PI	rDNA Registration Document Title
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05155 Michael Anderson RNAi studies of melanosomal related molecules ascertained in cell culture

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 8-0 for approval.

3. **Old Business**
rDNA # 05146

Dr. Meier reported on questions that were raised at the last IBC meeting regarding Dr. McCray's protocol #05146. He will ask Dr. McCray to provide a clarifying statement that can be added to the rDNARD regarding the plasmid DNA used in this project. The IBC members voted on the protocol, as amended.

Vote: 8-0 for approval.

4. **Training Materials**

A draft of the rDNA training program had been distributed to members for their review and comments. Members asked for more time to review the material and we will plan to discuss the draft at the next IBC meeting.

5. **New Business:**

Discussion of the possibility of revising our procedure to require that all PIs proposing projects involving work with rDNA complete rDNARDs, even if they think that the work is exempt under the *NIH Guidelines*

Recently we have been made aware that the American Heart Association is requiring documentation from applicant institutions that all projects submitted for review that involve rDNA, including those listed as exempt by the PIs, have IBC approval. This is an issue that has been discussed in the past, and Dr. Kirchhoff asked committee members for their recommendations regarding whether PIs who believe their proposed rDNA work is exempt under the *NIH Guidelines* should be required to complete rDNARDs. Under a procedure proposed by Ms. McGhan, all PIs who believe their rDNA research is exempt under the *NIH Guidelines* would complete rDNARDs. These would be reviewed by biosafety staff, and if they felt that the research was exempt and the IBC chair agreed, the rDNARDs would not go through full committee review. Committee members agreed that this proposed procedure was appropriate and workable. It was agreed, however, that the paperwork burden for PIs resulting from the implementation of this procedure would be substantial. In view of this it was decided that Dr. Kirchhoff and Ms. McGhan will discuss this matter with Dr. Wynes and that it will be discussed again at a future IBC meeting.

Next meeting will be September 26, 2005 at 3:30 p.m.

The meeting adjourned at 4:10 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: October 4, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of September 26, 2005

Members Present: Drs. Louis Kirchhoff, Brian Hanzelka, Aloysius Klingelhutz, Jeffery Meier, and Haley Sinn; Ms. Kim Lennox and Ms. Carol McGhan; ex-officio member Dr. David Wynes

Members Absent: Dr. Michael Parker and Mr. Douglas Herman;

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on September 12, 2005**
Dr. Klingelhutz made a motion, seconded by Ms. Lennox, to approve the minutes of the September 12, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
The following two protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05161	Larry Oberley	Delivery of mitochondria-targeted antioxidant enzymes to motor neurons for therapy in ALS mice

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, with ABSL2c for the work in mice.

Vote: 7-0 for approval.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05162	Beverly Davidson	Gene Vector Core 2 nd Quarter Vector Report

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 7-0 for approval.

3. Training Materials

A draft of the rDNA training program had been distributed to members for their review and comments. Members needed more time to review the material. Dr. Wynes asked that the draft be emailed to everyone again and the committee will discuss this at the next meeting.

4. Dr. Steve Varga rDNARD

Dr. Kirchhoff asked whether there were comments or concerns regarding the documents that had been sent to the committee, which included Dr. Kirchhoff's correspondence and notes from his interactions with Dr. Varga regarding questions which the committee had posed. Drs. Klingelhutz and Wynes inquired about the process. Dr. Kirchhoff explained that as discussed with Dr. Wynes and Ms. McGhan during a meeting several weeks ago, he intends to ask NIH/OBA for guidance on the issues raised by Dr. Varga's rDNARD, which have been discussed at previous IBC meetings.

5. Old Business - Discussion of procedures for projects that PIs believe are exempt under the *NIH Guidelines*.

Dr. Wynes felt that instead of requiring that rDNARDs be filled out by all PIs who are planning projects involving rDNA, a prudent approach would entail asking a series of questions on the Sponsored Programs memo that PIs now receive when they indicate on the routing form that their work involves rDNA, but is exempt from the *NIH Guidelines*. He had developed a list of 6 questions that follow the conditions under which recombinant molecules are considered exempt, as listed in the *NIH Guidelines*. The committee was in agreement that this method would provide a more reasonable balance. Dr. Kirchhoff and Ms. McGhan will work on refining the list of questions proposed by Dr. Wynes and will present them to the committee when revisions have been completed.

Next meeting will be October 10, 2005 at 3:30 p.m.

The meeting adjourned at 4:16 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: October 10, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of October 10, 2005

Members Present: Drs. Louis Kirchhoff, Aloysius Klingelhutz, Michael Parker, and Haley Sinn; Ms. Kim Lennox and Ms. Carol McGhan

Members Absent: Drs. Brian Hanzelka and Jeffery Meier, Mr. Douglas Herman and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on September 26, 2005**
Dr. Sinn made a motion, seconded by Ms. Lennox, to approve the minutes of the September 26, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
The following seven protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05146	Paul McCray/Varga	RNAi Interference of Respiratory Viruses

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, with ABSL2a for the work in mice.

Vote: 3-0 for approval. Dr. Sinn and Ms. Kim Lennox recused themselves from voting.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05163	Curt Sigmund	Role of Enhancers Regulating Renin Gene Expression

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 5-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05166	C Michael Knudson	Regulation of cell growth and oncogenesis by Bcl-2& Bax

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 5-0 for approval

rDNA#	PI	rDNA Registration Document Title
05167	Dawn Quelle	Defining the Role of a Novel Protein, NIAM, in Breast Cancer

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1. Dr. Kirchhoff noted that the approved rDNARD should clearly indicate that Dawn Quelle is the PI, rather than Van Thompkins, a graduate student. The rDNARD will be amended.

Vote: 5-0 for approval

rDNA#	PI	rDNA Registration Document Title
05168	Dawn Quelle	Role of Putative Tumor Suppressor, NIAM, in Breast Carcinoma

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 5-0 for approval

rDNA#	PI	rDNA Registration Document Title
05169	William Talman	Cardiovascular Response to Glutamate Nitric Oxide

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c and ABSL1 for FIV.

Vote: 5-0 for approval

rDNA#	PI	rDNA Registration Document Title
05171	Aloysius J. Klingelhutz	Role of HPV genes in immortalization

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5-0 for approval (Dr. Klingelhutz was not present for the vote.)

rDNA#	PI	rDNA Registration Document Title
05172	Michael Apicella	Studies of the LPS and Capsular Antigen of F. tularensis

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and BSL3.

Vote: 5-0 for approval

Dr. Klingelhutz joined the meeting at this time.

3. Old Business - Training Materials

Ms. McGhan noted that no comments from committee members had been received; however, Dr. James Walker, Director, HPO, had provided some suggestions for the process and course content. One suggestion was to place the NIH course on HPO's website and promote it through several methods, e.g., laboratory audits, LabNews (HPO's newsletter that is distributed to all laboratory departments and individual laboratories), Sponsored Programs mailings, etc. for at least a year. After that period of time, we may want to consider ways to be more effective in getting PIs to take the course. Members felt that was a reasonable suggestion and noted that it would also provide an opportunity to get feedback on the content of the course from the research community. Another suggestion made by Dr. Walker was to include information on the "dual use" issue in the course, but it was decided that it would be better to add dual use information when more guidance is available from the National Science Advisory Board for Biosecurity (NSABB).

4. New Business – rDNARD involving human subjects

Ms. McGhan informed IBC members that a newly submitted rDNARD involving human subjects will be included in the file that will be sent to members prior to the next meeting. As explained in E-mail messages sent to IBC members prior to today's meeting, it is anticipated that IBC members will be given access this week to the study protocol and related documents that are online through the HawkIRB, which is the Human Subject Office's online program for submission and review of IRB applications. There was some discussion about what members may want to review in the HawkIRB documents vs. the rDNARD.

Next meeting will be October 24, 2005 at 3:30 p.m.

The meeting adjourned at 4:07 p.m.

Minutes submitted by: Carol McGhan, CBSP

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: October 24, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of October 24, 2005

Members Present: Drs. Brian Hanzelka, Louis Kirchhoff, Jeffery Meier, Michael Parker, and Haley Sinn, and Ms. Kim Lennox

Members Absent: Dr. Aloysius Klingelhutz, ex-officio member Dr. David Wynes, Mr. Douglas Herman, and Ms. Carol McGhan, and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz and Ms. Merry Ibsen

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:40p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on October 10, 2005**
 Ms. Lennox made a motion, seconded by Dr. Parker, to approve the minutes of the October 10, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following twelve protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05164	David Sheff	Cancer Progression as Affected by Membrane Traffic Mediators

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Sinn noted that the Biosafety Office does not have record of Dr. Sheff previously working with recombinant DNA in Lentivirus. Dr. Meier suggested Dr. Sheff's previous experiments with Adenovirus and BSL2 work would be sufficient experience to work with a crippled Lentivirus. Dr. Kirchhoff requested clarification from Dr. Sheff regarding how the human tissue will be harvested and if IRB approval has been obtained. Ms. Kratz will contact Dr. Sheff and request this information. Dr. Kirchhoff asked to table the protocol pending further information. The members voted unanimously to table the document.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05165	David Sheff	Polarized Sorting in Subdomains of Recycling Endosomes

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6-0 for approval.

rDNA#	PI	rDNA Registration Document Title
05170	M. Sue O'Dorisio	Radioreceptor Guided Surgery Therapy in Neural Crest Tumors

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05173	Beverley Davidson	GTVC-Virus Production and Amplification Non-UI Investigators – 3 rd Quarter 2005

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05174	Lori Wallrath/Michael Henry	The Role of HP1-Hsalph in Breast Cancer Metastasis

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Parker stated that Lentiviral work in animals may be done at ABSL1. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05175	Christopher Stipp	Integrin Complexes in Testicular Germ Cell Tumor Motility

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05177	Pamela Geyer	Regulation of Tissue Specific Gene Expression

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05178	David Lubaroff	Enhancement of Anti-PSA T-Cell Responses by CpG Oligodeoxynucleotides

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Ms. Kratz asked for clarification on the animal containment level; Dr. Parker stated that the animal care facility assigns ABSL2c to all animal work involving adenovirus. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05179	Michael O'Donnell	A Phase I Study of the Safety and Tolerability of Intravesical Administration of SCH 721015 in Patients with Transitional Cell Carcinoma of the Bladder

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05180	Gail Bishop	B-Cell Signaling by the EBV Transforming Protein, LMP1

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05181	Byoung-Kwan Kim	Fermentation of 100 Liters E. coli

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Through e-mail correspondence with Dr. Sinn, Dr. Kim stated that he has been involved in recombinant DNA work since 1983 and large scale production since 1989. The committee determined that this work must be done at BSL2.

Vote: 6-0 for approval

rDNA#	PI	rDNA Registration Document Title
05182	Brad Jones	Construction of a Salmonella SL7207 lytB Mutant by Linear Transformation

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6-0 for approval

3. Old Business

rDNA#	PI	rDNA Registration Document Title
05088	Steve Varga	Pathogenesis of SARS-CoV

Dr. Meier made a motion, seconded by Dr. Sinn, to send a letter of inquiry to Dr. Kathryn Harris at NIH/OBA regarding the SARS-CoV/RSV work proposed by Dr. Varga in this rDNARD, and to send

it and related documents to the additionally, the rDNA Registration Document will be sent to the Office of the Vice President for Research for her consideration review and possible approval, with the understanding that authorization to do the work described in the rDNARD is contingent on approval both from the IBC and the OVPR. The members voted unanimously in favor of this motion to request further guidance from both Dr. Harris and the OVPR.

Dr. Kirchhoff indicated that recently he had contacted Dr. Varga by telephone to discuss (1) administrative and experimental progress relating to the rDNARD #04068, approved on April 4, 2004, covering SARS-CoV/influenza virus experiments, and (2) the administrative status of the SARS-CoV/RSV project described in the pending rDNARD #05088. Dr. Varga is the sole PI on both these rDNARDs. Dr. Varga indicated that he had not applied for and thus did not have authorization from the DVAMC or UI BSL3 committees to perform the experiments outlined in either of these two rDNARDs, and that specifically none of the SARS-CoV/influenza virus work covered by rDNARD #04068 had been undertaken. Dr. Varga did state, however, that Dr. Perlman either had submitted or would be submitting a request to the DVAMC BSL3 committee for authorization to do some of the experiments in question. Dr. Kirchhoff stated to Dr. Varga that if Dr. Perlman was going to be performing some of the SARS-CoV/RSV experiments, that Dr. Varga should withdraw the pending rDNARD (#05088) and submit a new rDNARD listing both Drs. Varga and Perlman as PI's. Subsequent to this conversation with Dr. Varga, Dr. Kirchhoff contacted Dr. Perlman by telephone and he indicated that he had not submitted to the DVAMC BSL3 committee a request for approval to do any of the work described in the Varga's rDNARDs and was not planning to do so.

NIH training course:

Dr. Sinn asked the committee if they had reviewed the NIH Training Course and associated test questions that were e-mailed to them last week. Dr. Hanzelka stated that the course and questions looked reasonable. Dr. Kirchhoff asked how the course will be advertised; Dr. Sinn stated that HPO will advertise through the LabNews publication and during the audits conducted by Ms. Kratz. There will be a general advertisement to all PI's, not just PI's currently working with rDNA. Dr. Sinn made a motion, seconded by Dr. Hanzelka, to post the NIH training course onto WebCT and broadly advertise to PI's that the course is available. The members voted unanimously to post the course and begin advertising.

4. New Business

The rDNA Registration Document has been updated. In the updated version PIs are asked to describe the relevant training and experience of personnel involved in the proposed project and, under in circumstances where training is required, the PI is asked to include information on how training will be provided, who will conduct the training, and what are the qualifications are of the person doing the training. Dr. Sinn sent the updated document out by e-mail to all committee members by E-mail on Friday, October 21. The revised updated version will be discussed at the next meeting.

The day the IBC meets will be changed from Mondays to Wednesdays due to a scheduling conflict this semester. The time of the meeting will remain the same, 3:30-5:00pm.

Dr. Kirchhoff related that inrequested information from Dr. Varga regarding his authorization to work with influenza and SARS. Dr. Varga stated that he is not authorized to work with SARS from the BSL3 committees at the VA, ML or UHL; however, Dr. Stanley Pearlman would be submitting a request for authorization. In a conversation with Dr. Kirchhoff, Dr. Pearlman stated that he has not requested BSL3 authorization nor will he be sending this request. Dr. Kirchhoff suggested the current rDNARD (#05088) be withdrawn and a new document submitted with both Drs. Varga and

Pearlman as PI's. Dr. Kirchhoff will forward all correspondence between himself and Dr. Varga to the committee members prior to the next meeting for further consideration.

Next meeting will be November 9, 2005 at 3:30p.m.

The meeting adjourned at 4:10p.m.

Minutes submitted by: Haley Sinn, Ph.D.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: November 14, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of November 9, 2005

Members Present: Drs. Brian Hanzelka, Louis Kirchhoff, Aloysius Klingelhutz, Jeffery Meier, Haley Sinn, Ms. Carol McGhan and ex-officio member Dr. David Wynes

Members Absent: Dr. Michael Parker, Mr. Douglas Herman and Ms. Kim Lennox

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on October 24, 2005**
 Dr. Meier made a motion, seconded by Dr. Hanzelka, to approve the minutes of the October 24, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following nine protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05164	David Sheff	Cancer Progression as Affected by Membrane Traffic Mediators

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05183	Beverly Davidson	GTVC- Vector Construction

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05184	Mark E. Anderson	Dr. Mark E. Anderson's Research Laboratory

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be

done at BSL2. As Dr. Anderson is a new investigator at UI, Ms McGhan will confirm his experience in working with the viral vectors proposed in this project.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05185	Brian Martin	Complement protection and anaphylatoxins in neuroinflammation

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABL2c.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05186	Michael Apicella, et al	Studies of LPS and capsular antigens of <i>F. tularensis</i>

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work, depending on the specific agent and type of work being performed, must be done at either BSL2 or BSL3 containment. Dr. Kirchhoff described the project for the members, as this proposal covers work with *Francisella* species being done by Drs. Apicella and McLendon, in addition to Dr. Nauseef's Inflammation Group at MTF.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05188	Timothy Ratliff	Development of Prostate Specific Adenoviruses for Gene Therapy

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABL2c. Ms. McGhan will confirm that the "RSV-Tk" listed in 1c should be corrected to read "HSV-Tk" prior to sending the approval letter to Dr. Ratliff.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05189	William Nauseef	Myeloperoxidase, oxidants, and phospholipase A2 in killing staphylococci

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05190	Johannes Hell	Subcellular localization of Cav1.2 by alfa-actinin

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05191	Johannes Hell	Characterization of Glutamate-Stimulated Pyk2 Recruitment to the Synapse and the Role of PSD-95

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05192	Andrew Russo	MLV-Luciferase Expression in MTC Tumor Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 6 approved, 0 opposed, 0 abstained

3. Old Business

Status of Steve Varga's protocol # 05088

Dr. Kirchhoff asked if there were additional comments on the draft memo he has written to Dr. Kathryn Harris at NIH/OBA regarding Dr. Varga's proposal to insert SARS-CoV genes into RSVΔSH and infect mice with the resulting constructs. Dr. Klingelutz inquired about the repercussions of a project being judged to be "dual use" and whether a project so designated could proceed or not. Dr. Kirchhoff reiterated that the process will involve more extensive review and that the issue will be passed to the OVPR for consideration. There was further discussion about the process related to the IBC's review of this protocol, the subsequent process for review by the OVPR, the precedent this will set, and policies that have been created at other institutions through mechanisms they have established to review proposals that present a potential public health and/or other concerns. Since there was a motion at the previous meeting to send a memo to Dr. Kathryn Harris, NIH/OBA, in addition to VPR Dr. Meredith Hay for their review and comments on the proposed experiments, these memos will be sent. At the next IBC meeting, there will be a vote on whether to approve Dr. Varga's protocol. If approved, Dr. Wynes stated that the rDNA protocol will not be released until the OVPR has signed off on the public policy issue related to "dual use."

Dr. Kirchhoff explained that in a recent discussion Dr. Varga, a new protocol would be submitted listing Dr. Stanley Perlman as a Co-PI and that he will withdraw the previously-submitted rDNARD #05088. Since Dr. Varga would like an opportunity to answer remaining questions the committee has, we discussed options for the best way to accomplish this. It was moved by Ms. McGhan and seconded by Dr. Klingelutz to have members submit questions to Dr. Kirchhoff who will send them to Drs. Varga and Perlman. Their written responses will be returned to the committee prior to the meeting. Drs. Varga and Perlman will be invited to discuss their answers with the committee, only if the committee receives their written responses prior to the IBC meeting and the committee wants clarifications or has additional questions.

Vote: 6 approved, 0 opposed, 0 abstained

Updated rDNA Registration Document

The most recently revised version of the rDNA Registration Document (rDNARD), dated 10/17/05, was brought to the attention of the committee. Dr. Sinn described the questions that were added in this version, which relate to the training and experience of personnel involved in the proposed projects; how training will be provided for individuals without the necessary experience; who will conduct this training; and the qualifications of the person doing the training. Dr. Sinn moved to accept the changes to the revised rDNARD (dated 10/17/05) and it was seconded by Dr. Hanzelka.

Vote: 6 approved, 0 opposed, 0 abstained

4. New Business

There was no new business.

Next meeting will be November 23, 2005 at 3:30 p.m. (Rescheduled for December 2nd at 1:00 p.m.)

The meeting adjourned at 4:25 p.m.

Minutes submitted by: Carol McGhan

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: November 29, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of November 23, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Haley Sinn, and Michael Parker; Mses. Kim Lennox and Carol McGhan; and ex-officio member Dr. David Wynes

Guests Present: Drs. Steven Varga and Stanley Perlman; Ms. Debbie Kratz

Members Absent: Drs. Brian Hanzelka and Aloysius Klingelhutz, and Mr. Douglas Herman

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:32 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. rDNA Registration Document #05203

Drs. Varga and Perlman were present during the initial portion of the meeting at the invitation of the chair for the purpose of answering questions from IBC members on the experiments involving HCoV-SARS and RSV they proposed in this recently submitted rDNARD. Questions asked by IBC members related to a variety of issues, including the following: (1) Why had the experiments approved by the IBC over 18 months ago involving the insertion of HCoV-SARS orfs into attenuated influenza and vaccinia viruses not been carried out as planned? (2) What procedures are in place for dealing with laboratorians who are potentially exposed to HCoV-SARS/RSV constructs or who become ill during periods in which they are working with such constructs? (3) Could more attenuated versions of RSV other than RSVrA2ΔSH, such as cp-52, be used in the proposed experiments? (4) Is the intent of this research to make a version of RSV that is more virulent than the wild type form? (5) What are the chances that the proposed research could produce a viral construct that is as virulent as HCoV-SARS or RSV? and (6) Could all the orfs of HCoV-SARS be studied just as effectively by using an attenuated mouse hepatitis virus rather than RSVrA2ΔSH as the recipient virus?

After Drs. Varga and Perlman responded to members' questions, they were dismissed. Dr. Kirchhoff reviewed the various issues relating to the HCoV-SARS/RSV experiments proposed in this rDNARD that have been examined by committee members. He called

attention to the second round of written questions that were sent to Drs. Varga and Perlman and their responses, all of which were forwarded to committee members electronically. These questions and answers are attached and are thereby incorporated as part of these minutes. In addition, Dr. Kirchhoff noted that he had not yet received a response to his letter to Dr. Kathryn Harris at NIH/OBA regarding the issue of dual use as it relates to the HCoV-SARS/RSV experiments proposed in this rDNARD. He also explained that recently he had written to Dr. Meredith Hay, the UI Vice President for Research regarding the rDNARD. Dr. Kirchhoff indicated that in the letter to Dr. Hay he explained that since the rDNARD involved experiments of concern, the work could only be performed after approval by the IBC, and the Office of the Vice President for Research.

During the discussion that followed, members expressed concerns regarding the adequacy of the assigned biosafety level, risks, and adequacy of protocols/mechanisms for BSL3 users who become ill (reporting, medical follow-up, and quarantine procedures). Dr. Wynes requested that Ms. McGhan ensure that procedures are in place that address IBC members' concerns related to how potential exposures and illnesses are reported and handled for the University's BSL3s. Ms. McGhan stated there are procedures in place and she will review and discuss them with Infectious Diseases and Infection Control staff.

Members voted as noted below with the understanding that if the rDNARD received IBC approval, the work could not be done until the Office of the Vice President for Research had also given approval.

rDNA#	PI	rDNA Registration Document Title
05203	Steven Varga	Pathogenesis of SARS-CoV

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL3 and ABSL3.

Vote: 4 approved, 1 opposed, 1 abstained

It was agreed that Ms. McGhan will notify Drs. Varga and Perlman that their rDNARD had been approved, but that the authorization to perform the experiments described in the approved rDNARD is contingent upon approval from the Office of the Vice President for Research. In addition, Dr. Kirchhoff will notify Dr. Hay that the IBC had approved this rDNARD.

Dr. Wynes requested that Ms. McGhan provide a timeframe to him regarding when the ML and CBRB BSL3 facilities would be available for use by Drs. Varga and Perlman.

2. Approval of minutes from meeting on November 9, 2005

Dr. Sinn made a motion, seconded by Dr. Meier, to approve the minutes of the November 9, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.

3. Protocols under review:

The following twelve protocols were considered:

rDNA#	PI	rDNA Registration Document Title
05194	John Lee	Use of HPV genes E6 & E7 to model HPV-associated squamous cell carcinoma of the head & neck

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05195	Bradley Dixon	p27Kip1 Regulation by G Protein Receptors in Vascular Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05196	Francis Abboud	Molecular Basis for Activation of Cardiovascular Sensory Afferents-Project V

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, ABSL1 for FIV and ABSL2c for adenovirus work.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05197	Paul McCray	Gene Transfer Using Integrating Vectors

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABL1 and 2c.

Vote: 5 approved, 0 opposed, 1 abstained

rDNA#	PI	rDNA Registration Document Title
05198	Paul McCray	Retroviral Gene Transfer to Airway Epithelial

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 containment.

Vote: 5 approved, 0 opposed, 1 abstained

rDNA#	PI	rDNA Registration Document Title
05199	Paul McCray	Expression and Function of Beta-defensins

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 5 approved, 0 opposed, 1 abstained

rDNA#	PI	rDNA Registration Document Title
05200	Paul McCray	Host Virus Interactions in HCoV-SARS Infection

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2. The last page will be corrected to indicate that no animals are used in this research.

Vote: 5 approved, 0 opposed, 1 abstained

rDNA#	PI	rDNA Registration Document Title
05201	Mark Stamnes	Expression of Shiga Toxin B Subunit in E-coli

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2; however the work is not exempt, as indicated, but falls under the category III-E.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05202	Charles A. Yeaman	Functions of the Sec6/8 Complex in Prostate Cancer

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05204	Prabhat Goswami	Antioxidant Enzymes 3-UTRS: Molecular Hotspots for Redox-based Therapy

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05205	Mary Wilson	Protective Immunity to Leishmania chagasi

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2b.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05206	Tannin Fuja	Investigating the invasive potential of activated vocal fold stellate cells in laryngeal cancer

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

4. Old Business

None.

5. New Business

None.

Next meeting will be December 7, 2005 at 3:30 p.m.

The meeting adjourned at 4:53 p.m.

Minutes submitted by: Carol McGhan.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee

Answers provided by Drs. Varga and Perlman on November 21, 2005, to questions posed by IBC members.

1. Please provide more details about your previous work experiences in BSL3 laboratories. Where were the laboratories and what organisms or viruses did you work with that required BSL3 containment?

Dr. Varga has had 3 months of experience working with HIV-1 in a BSL-3 laboratory at the University of Massachusetts Medical Center (UMMC) as well as 5 years of experience working with animals in a BSL-3 containment facility at UMMC during his graduate work using LCMV Clone 13. Lecia Pewe (laboratory technician) and Jason Netland (graduate student) have been trained and worked under Dr. Stanley Perlman's guidance in the University of Iowa Hygienic Laboratory and the Veterans Administration laboratory BLS-3 facilities. The Perlman laboratory has worked with HCoV-SARS for the past two years.

2. Dr. Varga indicated that when the HCoV-SARS orf6 was inserted into an attenuated strain of MHV, it enhanced the ability of this virus to replicate and made it more virulent. In addition, Dr. Varga indicated that if the pending rDNARD is approved, his first experiments will involve the insertion of orf6 into RSVrA2ΔSH. This increases our concern, as the introduction of orf6 into the mildly attenuated RSVrA2ΔSH may increase its ability to replicate and make it more virulent. The IBC carefully reviews proposed research in cases in which even highly attenuated virus strains are used, so your proposal to use this system in a manner that may result in a more virulent strain is troubling. What other systems could be used that would not raise these concerns? What other systems could be used to investigate the function of each of the proteins encoded by the HCoV-SARS orfs without using a human respiratory pathogen?

- A. When orf 6 was introduced into an attenuated MHV it resulted in a more virulent virus within infected animals, however this virulence did not attain a level close to the wild-type MHV.
- B. The RSVrA2ΔSH is an attenuated virus. There have been few studies utilizing this virus because it was quickly determined to be too attenuated for a viable vaccine candidate.
- C. Infection of chimpanzees with RSVrA2ΔSH resulted in reduced virus titers (40-fold) in the tracheal lavage fluid (as compared to wild-type RSV) and clinical disease was reduced to nearly background levels.
- D. We want to reiterate that we have proposed to utilize this recombinant virus under BSL-3 laboratory requirement.

3. What other systems could be used that would not raise these concerns?

We do not share the concerns regarding expression of orf6 by RSVrA2ΔSH. There are limited reverse genetics systems available that allow for the introduction of a foreign protein into a suitable pathogen that is capable of replicating in mouse lung tissue.

4. What other systems could be used to investigate the function of each of the proteins encoded by the HCoV-SARS orfs without using a human respiratory pathogen?

The only other respiratory RNA virus system available for the expression of foreign proteins is influenza virus and we continue to work on this system. However influenza virus does tolerate the expression of foreign proteins well.

5. If the RSVrA2ΔSH /mouse model is a useful system for studying proteins whose function is not known, one would expect that more research articles would have been published that document its use for this purpose. This is especially true since the articles we have been able to find that describe the level of attenuation of RSVrA2ΔSH were published in the late 1990s. Have you looked into why no descriptions of the use of RSVrA2ΔSH as a carrier virus to investigate protein function have been published?

The RSVrA2ΔSH is not a useful virus for studying the expression of a foreign protein because it is such an attenuated virus. However, we are interested in examining the expression of a HCoV-SARS protein in the mouse lung and therefore this attenuated virus is necessary because of its ability to be delivered into and replicate within mouse lung tissue.



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Date: December 7, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of December 7, 2005

Members Present: Drs. Brian Hanzelka, Louis Kirchhoff, Haley Sinn, and Mses. Kim Lennox and Carol McGhan

Guests Present: Ms. Debbie Kratz

Members Absent: Drs. Aloysius Klingelhutz, Jeffery Meier, Michael Parker and Mr. Douglas Herman; and ex-officio member Dr. David Wynes

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on November 23, 2005**
 Dr. Sinn made a motion, seconded by Ms. Lennox, to approve the minutes of the November 23, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following eight protocols were considered:

rDNA#	PI	rDNA Registration Document Title
05207	John Engelhardt	Redox-Mediated Mechanisms of NF-kappaB Activation to LPS and IL-1

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABS1.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05208	Tomomi Kuwana	Apoptosis

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1. The ABSL level will be deleted, as the frog eggs are not cultivated for any length of time and are not returned to Animal Care Facilities.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05209	Jon Houtman	Production of Bacterial and Mammalian Expression Vectors in E. coli and Their Use in Bacterial Strains and Human T Cell Lines

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05211	Jonathan Heusel	A Molecular Dissection of Specific NK Cell Activation

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABL2c.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05212	Beverly Davidson	MPS VII treatment using AAV4 and AAV5 vectors

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1 containment.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05213	Beverly Davidson	Preclinical Development of a gene therapy for Huntington Disease via RNA interference

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05214	Gary Hunninghake	Part 2 of Modulation of Acute Lung Injury

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05215	Steven Lentz	Role of asymmetric dimethylarginine in the endothelial dysfunction of hyperhomocysteinemia

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

3. Old Business

Dr. Kirchhoff reported that he received a response from Dr. Kathryn Harris, NIH/OBA, regarding his request for NIH/OBA's comments on Dr. Varga's rDNARD that proposed to insert orfs from the HCoV-SARS into an attenuated strain of RSV, RSVrA2ΔSH. In her response, Dr. Harris stated that OBA is "unable to provide specific advice on how to address any perceived dual use characteristics of this project."

Dr. Kirchhoff also informed the committee that he received a letter from Dr. Meredith Hay today in which she states that she has approved Drs. Varga and Perlman's rDNARD #05203. Consequently, an IBC approval memo will be sent to the PIs.

4. New Business

Ms. McGhan explained that an IRB administrator asked for the IBC's procedures regarding the way it addresses conflict of interest issues with respect to the review and approval of rDNA protocols. As there was no statement in our procedures, with input from Dr. and Dr. Wynes, a statement was developed and will be added to the IBC protocol on issues of conflict of interest. It will say, "If an IBC member is the investigator, or a spouse or dependent child of the member is involved in the project under review, or is part of the investigator's staff, he/she must recuse him/herself from reviewing and voting on the protocol."

Next meeting will be December 21, 2005 at 3:30 p.m.

The meeting adjourned at 3:48 p.m.

Minutes submitted by: Carol McGhan.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



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Date: December 21, 2005

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of December 21, 2005

Members Present: Drs. Louis Kirchhoff, Jeffery Meier, Michael Parker, and Haley Sinn

Members Absent: Drs. Brian Hanzelka and Aloysius Klingelhutz, Mr. Douglas Herman, Ms. Kim Lennox and Ms. Carol McGhan, and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on December 7, 2005**
 Dr. Sinn made a motion, seconded by Dr. Kirchhoff, to approve the minutes of the December 7, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following ten protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05216	Botond Banfi	Investigation of the Role of NADPH Oxidases in Innate Host Defense

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 3 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05217	John Engelhardt	Biology of Submucosal Gland Stem Cells in the Airway

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Kirchhoff asked for clarification regarding the plasmids that will be used in the protocol; Ms. Kratz stated that the plasmids will be pUC18 and pCDNA3.1. Dr. Parker stated that the proper containment level for ferrets is ABSL2d and he would like to further discuss containment for the animal experiments with Ms. McGhan when she returns. The committee determined that this work must be done at BSL2. Pending further discussion the voting was as follows: 3 approved, 0 opposed, 0 abstained.

rDNA#	PI	rDNA Registration Document Title
05220	Beverly Davidson	Gene Therapy and Enzyme Replacement for Batten Disease

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 3 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05221	John Stokes	O'Brien Kidney Research Center

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 3 approved, 0 opposed, 0 abstained

Dr. Jeffery Meier joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
05222	Fiorenza Ianzini	Modulation of Radiation-Induced Mitotic Catastrophe (MC) in Human Glioblastoma Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 4 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05223	Fiorenza Ianzini	Modulation of Radiation-Induced Mitotic Catastrophe (MC) in Human Colon Cancer Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Kirchhoff asked for clarification regarding the replication status of the adenoviral vector. Ms. Kratz stated that the adenoviral vector is replication defective due to an E1 deletion, only the p53 protein is wild-type; she will add this information to question 1f. The committee determined that this work must be done at BSL2.

Vote: 4 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05224	Fiorenza Ianzini	PCR cDNA Cloning

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1.

Vote: 4 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05225	Aliye Uc	Regulation of Heme Uptake and Transport in Caco-2 Cells

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 4 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05226	Daniel Eberl	Drosophila Deafness Genes: Molecular Function of Chordontonal Mechanoreceptors

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 4 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
05227	Daniel Berg/Thomas Griffith	Mechanisms of NSAID-Induced Inflammatory Bowel Disease in IL10-/-Mice

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 4 approved, 0 opposed, 0 abstained

3. Old Business

There was no old business.

4. New Business

The day the IBC meets will be changed from Wednesdays to Thursdays due to a scheduling conflict next semester. The time of the meeting will remain the same, 3:30-5:00pm.

Next meeting will be January 5, 2005 at 3:30p.m.

The meeting adjourned at 3:48p.m.

Minutes submitted by: Haley Sinn, Ph.D.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



Health Protection Office
100 HPO
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: January 6, 2006

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 6, 2006

Members Present: Drs. Brian Hanzelka, Louis Kirchhoff, Aloysius Klingelhutz, Jeffery Meier, and Haley Sinn

Members Absent: Dr. Michael Parker, Mr. Douglas Herman, Ms. Kim Lennox and Ms. Carol McGhan, and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

- 1. Approval of minutes from meeting on December 21, 2005**
Dr. Meier made a motion, seconded by Dr. Sinn, to approve the minutes of the December 21, 2005, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
- 2. Protocols under review:**
The following three protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05219	Gerene Denning, Dwight Look	Pseudomonas phenazines and airway inflammation

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05228	John Engelhardt	Generating a Ferret Model of Cystic Fibrosis

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Ms. Kratz asked for clarification regarding the ABSL for ferrets and stated that she would discuss containment for the ferret experiments with Dr. Parker when he is available. Dr. Klingelhutz asked for clarification on the ABSL for experiments involving adenovirus. Ms. Kratz pointed out that she had handwritten "ABSL2c for adenoviral experiments" onto the submitted rDNARD. The committee agreed that this work must be done at

BSL2. Pending clarification of the ABSL with Dr. Parker, the voting was as follows: 5 approved, 0 opposed, 0 abstained.

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05229	Robin Davisson, Ram Sharma	Role of Redox-Mediated Activation of NFkB and AP-1 in Neurogenic Hypertension

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, ABSL1 for FIV, and ABSL2c for Adenovirus.

Vote: 5 approved, 0 opposed, 0 abstained

3. Old Business

There was no old business.

4. New Business

There was no new business.

Next meeting will be January 19, 2005 at 3:30 p.m.

The meeting adjourned at 3:40 p.m.

Minutes submitted by: Haley Sinn, Ph.D.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



Health Protection Office
100 HPO
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: January 19, 2006

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of January 19, 2006

Members Present: Drs. Brian Hanzelka, Louis Kirchhoff, Aloysius Klingelhutz, Michael Parker, and Haley Sinn, Ms. Kim Lennox and Ms. Carol McGhan

Members Absent: Mr. Douglas Herman, Dr. Jeffery Meier, and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on January 5, 2006**
Dr. Klingelhutz made a motion, seconded by Ms. McGhan, to approve the minutes of the January 5, 2006, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
The following seven protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06003	Jacob Ijdo	How does Ehrlichia circumvent the respiratory burst in neutrophils

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 7 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06004	Gail Bishop	Molecular mechanisms of CD40 signaling to B lymphocytes

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1.

Vote: 7 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06007	Beverly Davidson	Disease-regulated RNA interference for Spinal Cerebellar Ataxia type 1 therapy

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Parker stated that there was an inconsistency in the ABSL listed in the table (ABSL2) and under question 2 (ABSL1). Ms. Kratz pointed out that she had handwritten "ABSL1 for AAV" under question 2 and will make this change in the table pending approval from Dr. Parker. The committee determined that this work must be done at BSL2 and ABSL1 for AAV.

Vote: 7 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06008	Curt Sigmund and Frank Faraci	Role of PPAR γ transcription factor in vascular function

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Parker stated that adenoviral work should be carried out at ABSL2c and transgenic work at ABSL1. The committee determined that this work must be done at BSL2.

Vote: 7 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06009	Mary Wilson, et.al.	Pathogenesis of Leishmaniasis: Host, Parasite and Vector

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 7 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06010	Rory Fisher and Daisuke Mayuzumi	Elucidation of endogenous RGS6 function in mammalian cell

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 7 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06012	Paul McCray	Gene therapy for cystic fibrosis lung disease, Project 3 – Targeting entry in epithelia with LCMV-FIV

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 1 abstained

3. Old Business

Ms. McGhan asked if anyone has looked at the NIH Guidelines training course on HPO's website or if anyone has received feedback from faculty and staff who have taken the course. No one on the committee has received any comments about the course. Ms. McGhan also stated that HPO is

advertising the course through Sponsored Programs and on the annual review letters that are sent out to Principal Investigators.

4. New Business

There was no new business.

Next meeting will be February 2, 2006 at 3:30 p.m.

The meeting adjourned at 3:40 p.m.

Minutes submitted by: Haley Sinn, Ph.D.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



Health Protection Office
 100 HPO
 Iowa City, IA 52242 – 1000
 Ph. 319-335-8501
 Fax 319-335-7564

Date: February 2, 2006

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 2, 2006

Members Present: Drs. Louis Kirchhoff, Aloysius Klingelutz, and Haley Sinn, Ms. Kim Lennox and Ms. Carol McGhan

Members Absent: Drs. Brian Hanzelka, Jeffery Meier, and Michael Parker, Mr. Douglas Herman, and ex-officio member Dr. David Wynes

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:36 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on January 19, 2006**
 Ms. Lennox made a motion, seconded by Ms. McGhan, to approve the minutes of the January 19, 2006, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following nine protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05176	Kathleen Sluka, Beverly Davidson	Central contributions to the pathobiology of fibromyalgia

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 4 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06002	A. Brent Carter	Hydrogen Peroxide and Asbestosis

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 4 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06005	Jim Jung-Ching Lin	Role of mXin α at myotendinous junctions

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 4 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06013	Eric Lazartigues	ACE2 gene therapy in neurogenic hypertension

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 4 approved, 0 opposed, 0 abstained

Dr. Klingelhutz joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
06015	Aliasger Salem	Non-viral gene delivery

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Kirchhoff asked that Dr. Salem expand his response to question 1c to include any inserted genes in the plasmid vectors. The committee determined that this work must be done at BSL2.

Vote: 4 approved, 0 opposed, 1 abstained

rDNA#	PI	rDNA Registration Document Title
06016	Vladimir Badovinac	Anti-tumor immunity mediated by early memory CD8 T cells after dendritic cells vaccination of tumor-bearing mice

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06017	Beverly Davidson, Scott Harper	Functional effects of Hes6 proteolysis on differentiation

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Ms. Lennox asked for clarification regarding the use of animals in this protocol. Ms. McGhan stated that mice will only be used as donors for neuronal tissue; no rDNA will be injected into the whole animal. However, Dr. Klingelhutz pointed out that the answer to question 1a refers to studying the development of neuroprogenitor cells in vivo. The Biosafety Office will contact Dr. Davidson to determine if any rDNA work will be carried out in whole animals. If animals are used for any purpose other than as donors, this protocol will be tabled; otherwise the committee has voted on the protocol with the understanding that rDNA work will only be carried out in cell cultures. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06018	Douglas Spitz, Michael Graham	Molecular imaging of responses to cancer therapy

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06019	Douglas Spitz	Enhanced apoptosis by targeting protein redox status

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

3. Old Business

There was no old business.

4. New Business

There was no new business.

Next meeting will be February 16, 2006 at 3:30 p.m.

The meeting adjourned at 3:52 p.m.

Minutes submitted by: Haley Sinn, Ph.D.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



Health Protection Office
100 HPO
Iowa City, IA 52242 – 1000
Ph. 319-335-8501
Fax 319-335-7564

Date: February 16, 2006

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of February 16, 2006

Members Present: Drs. Brian Hanzelka, Louis Kirchhoff, Aloysius Klingelhutz, Jeffery Meier, and Haley Sinn, Ms. Kim Lennox and Ms. Carol McGhan

Members Absent: Mr. Douglas Herman, Dr. Michael Parker, and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:33 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on February 2, 2006**
Ms. McGhan made a motion, seconded by Ms. Lennox, to approve the minutes of the February 2, 2006, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
The following five protocols were considered:

rDNA#	PI	rDNA Registration Document Title
06020	Paul McCray	Enhancing hepatocyte gene transfer for Hemophilia A

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Kirchhoff asked that Dr. McCray submit a final copy of his rDNA Registration Document, removing all hand editing of the text and clarifying if recombinant FIV will be used in this proposal. Ms. McGhan stated that FIV will not be used, but rather results from the previously completed experiments involving FIV will be compared with those obtained in the experiments outlined in the current proposal. Dr. Klingelhutz suggested that protocol numbers of previously approved rDNA Registration Documents addressing FIV recombinants be included in the final submitted document. The committee determined that this work must be done at BSL2 and ABSL2c.

Vote: 5 approved, 0 opposed, 1 abstained

rDNA#	PI	rDNA Registration Document Title
06021	Kris DeMali	Role of vinculin in epithelial cell-cell junctions

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Kirchhoff reiterated that the expressed

exoenzyme (C3) is a part of the *Clostridium botulinum* toxin gene but is not the toxin itself. The committee determined that this work must be done at BSL2.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06022	Douglas Trask and Jonathan Bock	Analysis of metastasis in oral cavity cancers using transfected cell lines

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Klingelutz asked that Dr. Trask include the use of small inhibitory RNAs and the pSilencer vector in his submitted table. The committee determined that this work must be done at BSL2 and ABSL1. Pending clarification of the table to be consistent with the written text, the voting was as follows:

6 approved, 0 opposed, 0 abstained

Dr. Jeffrey Meier joined the meeting at this time.

rDNA#	PI	rDNA Registration Document Title
06023	Brain Martin, Gregory Hageman, Richard Smith	Development of complement modulating therapeutics for AMD

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Klingelutz asked for clarification on the nature of the replication deficiency for BIV and that all laboratories in which recombinant work will be done be listed in the laboratory location section. Dr. Klingelutz also asked if the committee should require that Co- PIs sign the rDNA Registration Document in order to ensure that they are aware of the contents of the submitted document. Ms. Kratz stated that all Co-PIs receive a copy of the signed document after approval. The committee determined that this work must be done at BSL2, ABSL2c for Ad and ABLS1 for BIV.

Vote: 7 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06024	Aloysius Klingelutz	Progression of HPV infected cells to malignancy

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 6 approved, 0 opposed, 0 abstained

3. Old Business

There was no old business.

4. New Business

Dr. Kirchhoff asked that a meeting reminder be sent to all committee members on the day of the meeting. The Biosafety office will send out the reminder.

Next meeting will be March 2, 2006 at 3:30 p.m.

The meeting adjourned at 3:49 p.m.

Minutes submitted by: Haley Sinn, Ph.D.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



Health Protection Office
 100 HPO
 Iowa City, IA 52242 – 1000
 Ph. 319-335-8501
 Fax 319-335-7564

Date: March 2, 2006

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of March 2, 2006

Members Present: Drs. Louis Kirchhoff, Aloysius Klingelhutz, Jeffery Meier, and Haley Sinn, Ms. Kim Lennox and Ms. Carol McGhan

Members Absent: Drs. Brian Hanzelka and Michael Parker, Mr. Douglas Herman, and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Klingelhutz at 3:34 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on February 16, 2006**
 Dr. Meier made a motion, seconded by Ms. McGhan, to approve the minutes of the February 16, 2006, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following ten protocols were considered:

rDNA#	PI	rDNA Registration Document Title
06025	Jim J-C. Lin	Novel Xin protein in cardiac development and function

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06026	John Lee	Progression of HPV infected cells to malignancy

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, ABSL1 and ABSL2c for human lentiviral vector.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06027	Andrew Russo	Human CGRP promoter-luciferase transgenic mice

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
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06029	Beverly Davidson	Silencing Huntingtin with siRNA
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The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Klingelhutz asked if ABSL1 is the correct containment level for AAV work. Ms. McGhan stated that in prior discussions with Dr. Parker it was determined that the containment features of ABSL1 are sufficient for AAV work in animals; however, bench work with AAV is classified as BSL2. The committee determined that this work must be done at BSL2 and ABSL1.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
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06030	Daniel Weeks, Jose Manaligod, Heather Bartlett, Bryan Allen	Nkx2.5 and congenital heart defects in <i>Xenopus</i> and molecular genetics of ear development in <i>Xenopus laevis</i>
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The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
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06031	Michael Dailey	Investigating the molecular mechanisms of schizophrenia
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The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1 and ABSL1.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
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06032	Gregory Gray	Use of influenza virus reassortant VN5N1-PR8/CDC-RG reference strain in serologic assays
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The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. Dr. Klingelhutz asked if this work must be considered by the IBC under the *NIH Guidelines*. Dr. Kirchhoff stated that the use of the recombinant viral vector is similar to a question proposed to Dr. Katherine Harris in the past regarding researcher A passing a recombinant molecule to researcher B who uses the molecule in an organism other than *E. coli* K12. In this scenario Dr. Harris stated that the recombinant molecule was covered by the *NIH Guidelines*. The committee determined that this work must be done at BSL2 enhanced.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
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06034	Curt Sigmund, Kamal Rahmouni	Role and regulation of adipose angiotensinogen gene in obesity
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The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABL2c.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06035	Christopher Stipp and Michael Henry	Tetraspanin control mechanisms in integrin-mediated cell motility

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2 and ABL2c.

Vote: 6 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06036	Pamela Geyer	The role of Drosophila LEM domain proteins in nuclear function: implications for EDMD

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL1.

Vote: 6 approved, 0 opposed, 0 abstained

3. Old Business

There was no old business.

4. New Business

There was no new business.

Next meeting will be March 16, 2006 at 3:30 p.m.

The meeting adjourned at 3:49 p.m.

Minutes submitted by: Haley Sinn, Ph.D.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee



Health Protection Office
 100 HPO
 Iowa City, IA 52242 – 1000
 Ph. 319-335-8501
 Fax 319-335-7564

Date: March 16, 2006

To: Members of the Institutional Biosafety Committee (IBC; rDNA Committee)

Subject: Minutes of the IBC Meeting of March 16, 2006

Members Present: Drs. Brian Hanzelka, Louis Kirchhoff, Jeffery Meier, and Michael Parker; Ms. Carol McGhan

Members Absent: Drs. Aloysius Klingelutz and Haley Sinn; Mr. Douglas Herman, Ms Kim Lennox and ex-officio member Dr. David Wynes

Guest Present: Ms. Deborah Kratz

The meeting was held in 126 Grand Avenue Court (HPO Conference Room), and members not able to attend in person joined the meeting by conference call. The meeting was called to order by Dr. Kirchhoff at 3:35 p.m.

The meeting was closed because it included discussion of proprietary research information.

Business Agenda

1. **Approval of minutes from meeting on March 2, 2006**
 Ms McGhan made a motion, seconded by Dr. Hanzelka, to approve the minutes of the March 2, 2006, meeting. No revisions or corrections were suggested. The members voted unanimously to approve the minutes.
2. **Protocols under review:**
 The following five protocols were considered:

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
05218	Alexander Horswill	Novel Therapies for Pneumonic Plague Targeting Quorum-Sensing Components

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2. Dr. Kirchhoff inquired about Dr. Horswill's response to question 1i, indicating that no work would be done in other labs. It was clarified that the response was in reference to labs at the UI and not labs that are external to the UI, since this project was in collaboration with another institution (ISU).

Vote: 5 approved, 0 opposed, 0 abstained

<u>rDNA#</u>	<u>PI</u>	<u>rDNA Registration Document Title</u>
06037	Thomas Griffith	Induction of anti-tumor immunity using a TRAIL/Apo-2L encoding recombinant adenovirus

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2, and ABSL2c.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06038	Beverly Davidson	4 th Quarter GTVC Report: Virus Production/Amplification for Non-UI Investigators

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06041	Mario Ascoli	Regulation of Follitropin Actions (LFF)

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

rDNA#	PI	rDNA Registration Document Title
06042	Mario Ascoli	Regulation of Follitropin Actions (FLL)

The review of this proposed research involved the consideration of containment level, facilities, procedures, practices, and investigator experience. The committee determined that this work must be done at BSL2.

Vote: 5 approved, 0 opposed, 0 abstained

3. **Old Business**

At Dr. Kirchhoff's request, Ms. McGhan gave the members an update of the project that has been under development for quite some time to create an rDNARD application and submission process that is available online. We have recently begun working on this again. A major delay had to do with the fact that the programmer who had been working on this left the UI. He is now under contract to complete this task and biosafety staff is working with him to complete this.

4. **New Business**

Ms. McGhan stated that she had received a fax from the Sunshine Project today, requesting IBC minutes since May 2003. She will discuss the request with Dr. Wynes and Ms. Grainne Martin before providing any of the requested information.

Next meeting will be March 30, 2006 at 3:30 p.m.

The meeting adjourned at 3:46 p.m.

Minutes submitted by: Carol McGhan, Biological Safety Officer.

Minutes approved by: Louis V. Kirchhoff, M.D., M.P.H., Chair, Institutional Biosafety Committee