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rick.johnson@ndsu.edu

April 26, 2006

Mr. Edward H. Hammond
Director, Sunshine Project
101 West 6th Street, Suite 607
Austin, TX 78701

RE: Request for NDSU Institutional Biosafety Committee Meeting Minutes

Dear Mr. Hammond:

Pursuant to your request of March 15, 2006, enclosed are copies of NDSU IBC's minutes for meetings held since May 1, 2003.

One sentence is redacted in the June 24, 2003, minutes per 7 U.S.C. 8401 (h).

With regard to your question on written policies, see:
<http://www.ndsu.nodak.edu/policy/347.htm>.

Sincerely,



Rick D. Johnson
General Counsel

Enc.

cc: VP Boudjouk
Val Kettner
David Berryhill
Pierre Freeman

doesn't
apply
to NDSU...
he's a
lawyer!

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Institutional Biosafety Committee

Office of the Vice President for Research, Creative Activities & Technology Transfer

1735 NDSU Research Park Drive

P.O. Box 5756

Fargo, ND 58105-5756

**Institutional Biosafety Committee
Meeting Minutes
June 24, 2003**

Meeting held: NDSU Memorial Union - Plains Room, 10 a.m.

Members present: D. Berryhill, D. Jensen, J. Weiland, D. Doetskott, L. Reynolds, W. Diamanti, C. Logue, T. Grosz

Members absent: G. Secor, M. Berg, R. Roehrdanz, V. Kettner

Guests present: Shane Stafslein, Tom Ready, James Bahr, Jason Greenwood

The meeting was called to order at 10:10 am by David Berryhill, Chair.

OLD BUSINESS:

Minutes

David called for any changes or additions to the minutes of the March 2003, meeting. A motion was made to approve (Jensen / Doetskott) and passed unanimously.

Inder Sehgal has left NDSU, and is no longer on the committee. The Dean of Pharmacy will be consulted for his replacement.

NEW BUSINESS:

Review of New Protocols:

“Biofilm Analysis and Biodetection”

McCarthy, Greg, Tom Ready and Shane Stafslein – Dept. of Center for Nanoscale Science and Engineering, Protocol #B03019

The protocol was summarized by the investigators. The ultimate goal is to develop sensors to detect chemical and biological warfare agents. Initial tests with the sensors will involve aerosolizing pesticides and non-pathogenic microbial strains inside a

custom-designed testing chamber within a fume hood. The antibody-based sensors would be removed for testing, and the bell jar either flushed with heated air or bleach, and vented through an activated carbon filter, and a HEPA filter. A prototype of the testing chamber is in development, and the investigators are seeking the committee's input on the biosafety aspects of the design.

The committee suggested use of a certified non-pathogen (ATCC is recommended as a source), mounting a UV light in the hood (to sterilize any microbes potentially escaping from the jar), use of a second HEPA filter, and using a BSC instead of a fume hood. A motion was made to accept the protocol (Berryhill/Logue), contingent on inspection and oversight and by the IBC Chair. Biosafety Level 1 is to be used for this work. Motion carried unanimously.

"Development of Glyphosate resistant HRSW"

M. Mergoum – Dept. of Plant Sciences, Protocol #B03016

Discussion followed, and a motion was made to accept the IBC chair's approval, based on prior approval by a federal agency - APHIS (Jensen/Logue). Motion carried unanimously.

"Agronomic Evaluation of Glyphosate-Resistant Wheat"

K. Howatt – Dept. of Plant Sciences, Protocol #B03015

Discussion followed, and a motion was made to accept the IBC chair's approval, based on prior approval by a federal agency - APHIS (Doetkott/Logue). Motion carried unanimously.

"Effects of flaxseed supplementation on reducing risk of diabetes and cardiovascular disease development in individuals with impaired glucose tolerance"

Y. Rhee – Dept. of Health, Nutrition & Exercise Sciences, Protocol #B03017

Discussion followed, and a motion was made to accept the IBC chair's prior approval for the use of human blood (Logue/Weiland). Biosafety Level 2 is to be used for this work. Motion carried unanimously.

"Evaluation of Glyphosate-Resistant Alfalfa"

K. Howatt – Dept. of Plant Sciences, Protocol #B03018

Discussion followed, and a motion was made to accept the protocol (Logue/Jensen). Motion carried unanimously.

“Transformation of barley and durum with antifungal and antitoxin genes”

L. Dahleen – Dept. of USDA-ARS, Northern Crops Science Lab, Protocol #B03020

Project is not exempt, as whole plants will be transformed. Discussion followed, and a motion was made to accept the protocol (Doetkott/Logue). Biosafety Level 1-P is to be used for this work. Motion carried unanimously.

Discussion followed concerning development of a continuing review form, similar to those for animal protocols with the IACUC. Ongoing projects could be updated with this, instead of submitting a completely new protocol every year.

Also discussed was the training requirement for recombinant DNA projects. Several personnel involved on the project did not complete. It was mentioned that, unless a directive comes from the top, USDA personnel would not be likely to do it, since there are a large number of other training requirements. John will mention it to the center director, and will report back to the committee.

“Development of multipurpose potato cultivars with enhance quality, disease and pest resistance”

A. Thompson – Dept. of Plant Sciences, Protocol #B03021

Protocol was previously voted on and accepted by electronic mail.

“A Genomic Approach to Investigate Root Bud Dormancy”

W. Chao – Dept. of USDA-ARS, Protocol #B03022

Discussion followed, and a motion was made to accept the protocol as ‘exempt’ from NIH Guidelines (Weiland/Jensen). Biosafety Level 1 is to be used for this work. Motion carried unanimously.

DISCUSSION ITEMS:

Select agents update: D. Berryhill attended the ASM national meeting recently, and presented an update on the select agents program. He presented some statistics on the inquiries and responses, and development of the regulations. [REDACTED]

Memorandum of Understanding between NDSU and USDA for review of IBC protocols:

Over a year ago, the IBC had discussed this with the USDA, and had come to a informal agreement that the NDSU IBC would review all USDA projects that use recombinant DNA. The University attorney was consulted, and although such a document was believed to have been in existence, it could not be located. Earlier this year, the

University attorney's office contacted the IBC director to inquire about drafting a new document, which was reviewed today. It was noted that the ARS office in Fort Collins, CO handles all MOU's for the USDA. J. Weiland will get their comments on this agreement.

ANNOUNCEMENTS:

Next meeting date to be announced.

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Institutional Biosafety Committee

*Office of the Vice President for Research, Creative Activities & Technology Transfer
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**Institutional Biosafety Committee
Meeting Minutes
September 9, 2003**

Meeting held: NDSU Memorial Union - Plains Room, 10 a.m.

Members present: D. Berryhill, C. Logue, G. Secor, L.Reynolds, J. Sheng, D. Doetkott, D. Jensen, R. Roehrdanz, S.Iszler for M. Berg, V. Kettner, P. Freeman

Members absent: J. Weiland, W. Diamanti

Guests present: T. Grosz

The meeting was called to order at 10:05 a.m.by David Berryhill, Chair.

OLD BUSINESS:

Minutes

Berryhill called for any changes or additions to the minutes of the June 24, 2003, meeting. A motion was made to approve (Secor / Logue) and passed unanimously.

NEW BUSINESS:

Review of New Protocols:

"Economics of Bovine Leptin Genotyping"
Eric DeVuyst – Dept. of Agribusiness and Applied Economics

EXEMPT– Protocol #B04001

A motion was made to accept the IBC Chair's approval (Jensen/Logue). Biosafety Level 1 is to be used for this work. Motion carried unanimously.

**“Lipotrope Stimulates Breast Cancer Cell Death”
Chung Park – Dept. of Animal and Range Sciences**

EXEMPT– Protocol #B04002

A motion was made to accept the protocol (Secor/Sheng). Biosafety Level 1 is to be used for this work. Motion carried unanimously.

**“PAPS Biosynthesis and Hydroxysteroid/Alcohol Sulfation”
Jonathan Sheng – Dept. of Pharmaceutical Sciences**

EXEMPT– Protocol #B04003

Dr. Sheng gave a brief explanation of the protocol, and a motion was made to accept it (Doetskott/Secor). Biosafety Level 2 is to be used for this work. Dr. Sheng abstained from voting. Motion carried unanimously.

Progress Reports:

**“Sucrose Accumulation and Retention in Sugarbeet”
Karen Klotz – USDA-ARS-RRVARC-NCSL**

NON-EXEMPT– Protocol #B02057

A question was raised as to whether this needed to be reviewed. Once it was approved did it need to be reviewed? Thoughts were that there should be follow up annually. The chair asked the Director to clarify the matter as to exempt and non-exempt whole plant transformations. A motion was made to receive the progress report (Secor/Jensen). Motion carried unanimously.

Change in Protocol:

**“Immunization of Mice Against a Nematode Parasite”
Dr. M. Robinson replaced by Dr. E. Berry, Veterinary and Microbiological Sciences
Protocol #B02026**

A motion was made to accept the change in principal investigator to Eugene Berry (Logue/Jensen). Motion carried unanimously.

Meeting Adjourned, 10:20 a.m.

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**Institutional Biosafety Committee
Meeting Minutes
November 19th, 2003**

Meeting held: NDSU Memorial Union—Plains Room 10 a.m.

Members present: D. Berryhill, C. Logue, J. Sheng, D. Doetskott, D. Jensen, R. Roehrdanz, S. Iszler
for M. Berg, P. Freeman, W. Diamanti

Members absent: G. Secor, L. Reynolds, V. Kettner, J. Weiland

Guest present: Jolean Pederson

The meeting was called to order at 10:10 a.m. By David Berryhill, Chair.

OLD BUSINESS: _____

- The Chair welcomed all members and guest. Introductions were given to our guest Jolean Pederson from the Office of Safety and Environmental Health
- The Chair called for any changes or additions to the minutes of the September 9th 2003 meeting. A motion was made to approve (Doetskott, Sheng) and passed unanimously.

NEW BUSINESS: _____

Review of New Protocols:

**“Molecular Analysis of Biological Organisms”
Phillip McClean - Department of Plant Sciences**

EXEMPT - Protocol # B04004

A motion was made to accept the IBC Chair's approval (Doetskott, Logue). Concerns were immediately raised about blanket approval for all of the PI's work. A motion was made to table the protocol until further detailed explanations and specifics to protocol could be obtained. The committee is requesting specifically that the title be more specific, the start date and end date be more applicable to the project, section III should provide a description as indicated, Section VII should indicate the room numbers applicable to where the work will be performed so that the proper Biosafety level can be assured and in section VIII should list all of those that will be working on this project. The committee decided to ask for specific protocols for each project if there is more than one that the PI had intended to cover in this attempt and that they would not allow blanket approval. Motion to table until further concerns were met and specific protocols for each project was obtained, was carried unanimously.

“Analysis of Acetyl-CoA Carboxylase Genes from Wild Oat”

Michael J. Christoffers - Department of Plant Sciences

EXEMPT - Protocol # B04005

A motion was made to accept the protocol (Rorhdanz/Doetskott). Biosafety level 1 is to be used for this work. No concerns were raised regarding this project. Motion carried Unanimously.

“Characterization of the Wheat Genomes and Economically Important Genes”

Xiwen Cai - Department of Plant Sciences,

EXEMPT - Protocol # B04006

A motion was made to accept the protocol (Doetskott/Jensen). It was stated that radiation safety approval had been obtained for this protocol already. Concerns with the location of the project were raised. Biosafety level 1 is to be used for this project. Motion carried pending clarification of research activity room #s and buildings.

“Design of gp120 Miniprotein Mimics”

Mahesh Jaseja - Chemistry,

EXEMPT - Protocol # B04007

A motion was made to accept the protocol (Logue/Jenson). Biosafety level 1 will be used to for this work. Concerns were raised that there was no specific description on page two, section III. Concerns were also raised as to the specifics on plasmids and host cells. Concerns were raised on the location of the work such as room numbers and buildings. Motion carried pending the clarification in section III and the specifics in section IV unanimously.

“Molecular Techniques for MICR 486”

Eugene Berry - Veterinary and Microbiological Sciences

EXEMPT - Protocol # B04008

A motion was made to accept the protocol (Sheng/Doetskott). Biosafety level 1 will be used to for this work. It was pointed out that the Director incorrectly circled the Human Blood category at the top of the protocol and it was noted that it should not have. Motion carried unanimously.

Progress Reports:

None at this time

Change in Protocol:

None at this time

-DISCUSSION ITEMS: _____

- It was discussed that the protocol form be revised so that room numbers and buildings are filled in accordingly and so that it is more clearly stated for the PI. Section III also needs to have some revisions with respect to NDSU has the capability for BL-3 research facilities.
- A brief discussion was also started concerning whether the students enrolled in courses needed to be on protocols. Should there be a course list submitted to the IBC. Our committee came to the conclusion that it was not necessary and it was up to the instructor per class for the responsible conduct and safety to the class and their actions.
- The director addressed the Graduate School's stance on the students and how OSPA is assisting the graduate school.
- OSEH has put together new signage for the biosafety labs and they would distribute them to the committee via listserv for comment.

RECENT POSTINGS TO IBC LISTERV: _____

- Survey of IBC's from ABSA Meeting in October: The director gave a quick overview and asked if there were any comments on the presentation sent to the committee. No comments were made.

ANNOUNCEMENTS: _____

- Next meeting date to be announced

Meeting adjourned 10:35am.

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**Institutional Biosafety Committee
Meeting Minutes
February 10, 2004**

Meeting held: NDSU Memorial Union, Badlands Room

Members present: D. Beryhill, C. Logue, G. Secor, P. Freeman, D. Jensen, J. Weiland, B. Diamanti, J. Sheng

Members absent: L. Reynolds, D. Doetkott, R. Roehrdanz, V. Kettner

Guest present: None

David Berryhill, Chair, called the meeting to order at 9:04 a.m.

OLD BUSINESS: _____

- The Chair welcomed all members.
- The chair called for any changes or additions to the minutes of the November 10th 2003 meeting. A motion was made to approve (Secor/Jensen) and passed unanimously.
- Signage for BSL labs. A short discussion occurred concerning advertising the biological agents within each lab. Some security concerns were raised. The Director was asked to look into the regulations from NIH and BMBL – 4 and to advise the committee on what needs to be disseminated to the labs. First responders and safety issues are of concern relating to signage.
- Updated the IBC protocols. The Director updated the committee on the progress of the protocol forms and the revisions.
 - Default in section IV was changed to be “No” rather than “Yes”
 - Adding wording to specify room numbers, building names and addresses in section VII.
 - BSL-3 diagnostic lab is only for diagnostic purposes and not intended for experimentation or research. }

New protocols are being uploaded as we meet.

NEW BUSINESS: _____

Review of New Protocols:

“Biotechnology of Common Bean”

Phillip McClean, Department of Plant Sciences,

EXEMPT - Protocol #B04004

A motion was made to accept the IBC Chair's approval (Secor/Logue). Biosafety Level 1 is to be used for this work. The committee requested that confirmation in section II was really “No” not “Yes”, as defaults are set to “Yes ‘. Signatures were obtained on the protocol from the chair of the department. Motion carried unanimously.

“Effects of Leptin Genotyping on Feed Intake and Efficiency”

Marc Bauer, Department of Animal Range Sciences,

EXEMPT - Protocol # B04009

A motion was made to accept the protocol (Jensen/Secor). Biosafety Level 1 is to be used for this work. Motion carried unanimously.

“Characterization of Infection of Wheat by Stagonospora Nodorum”

Tim Friesen, USDA-ARS,

EXEMPT - Protocol #B04012

A motion was made to accept the IBC Chair's approval (Secor/Sheng). Biosafety Level 1 is to be used for this work. Motion carried unanimously.

“Spectroscopic Studies of Hem:Hemopexin”

Kenton Rodgers, Chemistry & Molecular Biology,

EXEMPT - Protocol #B04013

A motion was made to accept the protocol (Jensen/Logue). Biosafety Level 2 is to be used for this work. This is a blood plasma project where a local blood service provider has screened the product. The only product will be plasma given to the researcher and only a protein is of interest. Bloodborne pathogen training has been scheduled for the individuals involved by Bill Diamanti. Motion carried unanimously.

“Genetic Modification of the fungal genus Pyrenophora”

Jack Rasmussen, Plant Pathology,

EXEMPT – Protocol # B04014

A protocol was introduced during the meeting as a late submission. It was handed out to all present members and was reviewed by all present. A general discussion ensued within the committee about completeness. A motion was made to accept the protocol (Secor/Sheng). Biosafety Level 2 is to be used for this work. Training requirements have been met and exempt status was emailed to the Director clarifying why it was exempt. Motion carried unanimously.

Progress Reports:

The Director is in the process of evaluating the files and contacting all possible PI's for reports.

Change in Protocol:

None at this time

DISCUSSION ITEMS: _____

- Progress Report Form – This would be for non-exempt status protocols. This would be sent out electronically to each PI. After they fill it out online they can then print it off and send in hard copy with signature. **Committee comments were that it would be nice if it could be electronic and the email could substitute for a signature.**
- Occupational Safety and Health – OSEH role in the IBC. **The Director was asked to look into the role that the OSEH representative should play in the IBC and how they and their department should work with the IBC. What are regulations and needs?**
- Call for discussion items:

RECENT POSTINGS TO IBC LISTERV: _____

- None

ANNOUNCEMENTS: _____

- Next meeting date to be announced

Meeting Adjourned at 9:50 a.m.

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**Institutional Biosafety Committee
Meeting Minutes
October 13th, 2004**

Meeting held: NDSU Memorial Union, Plains Room

Members present: D. Beryhill, K. Kooren, P. Freeman, D. Jensen, J. Weiland, J. Sheng, L. Reynolds, R. Roehrdanz, C. Logue

Members absent: G. Secor, B. Diamanti, K. Kettner, D. Doetkott

Guest present: None

David Berryhill, Chair, called the meeting to order at 12:05 p.m.

OLD BUSINESS: _____

- The Chair welcomed all members.
- The chair called for any changes or additions to the minutes of the May 4th 2004 meeting. A motion was made to approve the minutes. The motion passed unanimously.

NEW BUSINESS: _____

Review of New Protocols:

“High resolution mapping of the Snn1 gene in wheat”, Justin Faris, USDA_ARS NCSL,

EXEMPT - Protocol # B04027

A motion was made to accept the protocol (Weiland/Jensen), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-E 6 of the NIH guidelines. Motion carried unanimously.

“Partial gene-replacement in yeast with the Acetyl-CoA carboxylase gene of wild oat”, Michael Christoffers, Plant Sciences,

EXEMPT - Protocol # B04028

A motion was made to accept the protocol (Jensen/Logue), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-E 6 of the NIH guidelines. Motion carried unanimously.

“Methods for Detection of cryptosporidium parvum”, John McEvoy, Vet and Micro Sciences,

INFECT Agent - Protocol # B04029

A motion was made to accept the protocol (Logue/Weiland), Biosafety level 2 is to be used for this project with appropriate hoods. Motion carried unanimously.

“Risk Assessment of E Coli 0157:H7 and salmonella in North Dakota feedlot cattle”, Margaret Khaita, Vet and Micro Sciences,

INFECT Agent - Protocol # B04030

A motion was made to accept the protocol (Logue/Jensen), Biosafety level 2 is to be used for this project with appropriate hoods. Motion carried unanimously.

“Aspergillus fumigatus-induced allergic airway disease: a murine model of human asthma”, Jane Schuh, Vet and Micro Sciences,

INFECT Agent - Protocol # B05001

A motion was made to accept the protocol (Weiland/Kooren), Biosafety level 2 is to be used for this project with appropriate hoods. Motion carried unanimously.

“Biochemical studies on cytosolic sulfotransferase and PAPAS synthetases”,

Jonathan Sheng, Pharmaceutical Sciences,

EXEMPT, Human Blood and Tissue - Protocol # B05002

A motion was made to accept the protocol (Logue/Jensen), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-E 1 NIH guidelines. Motion carried unanimously, *J.Sheng abstained from voting.*

“Methyl donor excess alters DNA Methylation of breast cancer cell lines” Chung Park, Animal & Range Sciences,

EXEMPT, Human Blood and Tissue - Protocol # B05003

A motion was made to accept the protocol (Roehrdanz/Logue), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-E 1 of the NIH guidelines. Motion carried unanimously.

“Analysis of virulence capacity of Escherichia Coli isolates from multiple animal species”, Penny Gibbs, Vet and Micro Sciences,

EXEMPT, INFECT. Agent - Protocol # B05004

A motion was made to accept the protocol (Logue/Sheng), Biosafety level 2 is to be used for this project within appropriate hoods. Exempt status clarified as exempt by I-B of the NIH guidelines. Motion carried unanimously.

“Analysis of the virulence capacity of Enterobacter Sakazakii”, Penny Gibbs, Vet and Micro Sciences,

EXEMPT, INFECT. Agent - Protocol # B05005

A motion was made to accept the protocol (Weiland/Logue), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by I-B of the NIH guidelines. Motion carried unanimously.

“Mechanism of Aer Mediated gene regulation in E. Coli” Birgit Pruess, Vet and Micro Sciences,

EXEMPT - Protocol # B05006

A motion was made to accept the protocol (Logue/Kooren), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-E 3 of the NIH guidelines. Motion carried unanimously.

“Functional genomics in Yersinia Enterocolitica” Birgit Pruess, Vet and Micro Sciences,

EXEMPT - Protocol # B05007

A motion was made to accept the protocol (Logue/Roehrdanz), Biosafety level 2 is to be used for this project within appropriate hoods. Exempt status clarified as exempt by III-E 3 of the NIH guidelines. Motion carried unanimously.

“Accuracy of Blood Glucose Monitors” Donald Miller, Pharmacy, Human Blood and Tissue - Protocol # B05009

A motion was made to accept the protocol (Jensen/Sheng), Biosafety level 2 is to be used for this project. Motion carried unanimously.

“Elucidating Defense Mechanisms of Resistance to Pyronophora tritici-repnetis in Wheat” Tika Adhikari, Plant Pathology,

EXEMPT - Protocol # B05010

The committee requested that this protocol be held over for review until a new submission can be received.

“The Effect of Delayed Treatment or No Treatment in a Clinical Mastitis Culturing and Treatment Program” Sarah Wagner, Vet and Micro Sciences,

INFECT. Agents - Protocol # B05011

A motion was made to accept the protocol (Weiland/Logue), Biosafety level 1 is to be used for this project. Motion carried unanimously.

Progress Reports:

To be emailed and discussed at further meetings

- 63 notices were sent out to request an update for Exempted protocols that were approved over a year ago.
- 31 of 63 needed changes or have been closed. (Mostly personnel changes)

Change in Protocol:

None at this time

DISCUSSION ITEMS: _____

All Items will be postponed until next the next meeting

- Safe Operating Procedure for tissue culture work in Sudro Hall
- Revising training Modules, what would the committee like to see?

- Developing a policy manual, what would the committee like to include or see?
- Call for discussion items - None

RECENT POSTINGS TO IBC LISTERV: _____

- None at this time

ANNOUNCEMENTS: _____

- Next meeting date, to be announced

Meeting Adjourned 1:15 p.m.

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**Institutional Biosafety Committee
Meeting Minutes
December 9th, 2004**

Meeting held: NDSU Memorial Union, Plains Room

Members present: D. Beryhill, K. Kooren, P. Freeman, D. Jensen, J. Weiland, J. Sheng, L. Reynolds, R. Roehrdanz, C. Logue, D. Doetskott, W. Dai

Members absent: G. Secor, B. Diamanti, K. Kettner,

Guest present: None

David Berryhill, Chair, called the meeting to order at 10 a.m.

OLD BUSINESS: _____

- The Chair welcomed all members and we introduced our new member W. Dai.
- The chair called for any changes or additions to the minutes of the October 13th 2004 meeting. A motion was made to approve the minutes. The motion passed unanimously.

NEW BUSINESS: _____

Review of New Protocols:

"Biologically-Based Weed management: Fundamental research on Dormancy and the Genetics of Weeds", Micheal Foley, USDA-ARS,

EXEMPT - Protocol # B05012

A motion was made to accept the protocol (Jensen/Roerhdanz), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-F 6 of the NIH guidelines. Motion carried unanimously.

"Characterization and Utilization of Novel Genes Conferring meiotic chromosome non-reduction in a Helianthus californicus accession" Chao-Chien Jan, USDA-ARS, EXEMPT - Protocol # B05013

A motion was made to accept the protocol (Doetskott/Weiland), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-F 1 of the NIH guidelines. Motion carried unanimously.

**"Cloning and Characterization of a downy mildew resistance gene from a new wild annual sunflower source" Jinguo Hu, USDA-ARS,
EXEMPT - Protocol # B05014**

A motion was made to accept the protocol (Logue/Jensen), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-F 1 of the NIH guidelines. Committee wanted further communication to the PI for a better description with greater detail provided in protocol description. Motion carried unanimously.

**"Using genomics and genetics to enhance disease resistance and quality in hard red spring and durum wheat", Yin-Shan Tai, USDA-ARS,
EXEMPT - Protocol # B05015**

A motion was made to accept the protocol (Doetskott/Logue), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-E 2 of the NIH guidelines. The committee requested that the greenhouse space used will be confirmed by the Director of the committee to assure BSL-2 Plant use. Motion carried unanimously.

**"Elucidating Defense Mechanisms of Resistance to Pyronophora tritici-repnetis in Wheat" Tika Adhikari, Plant Pathology,
EXEMPT - Protocol # B05010**

A motion was made to accept the protocol (Reynolds/Doetskott), Biosafety level 1 is to be used for this project. Exempt status clarified as exempt by III-F 4, 6 of the NIH guidelines. Section II was still not clear to the committee. The committee would like the PI to work with the departmental representative Gary Secor to assist in the information and filing of the protocol and provide what genes are sequenced and what is appropriate BS- level. Motion was modified (Kooren/Doetskott) to table indefinitely. Motion carried unanimously

Progress Reports:

None at this time

Change in Protocol:

None at this time

DISCUSSION ITEMS: _____

- Who certifies the BSL-3 lab space? There were some concerns raised regarding the doors.
- Call for discussion items - None

apparently not diagnostic?

RECENT POSTINGS TO IBC LISTERV: _____

- None at this time

ANNOUNCEMENTS: _____

- Next meeting date, February 10th 2005

Meeting Adjourned 10:55 a.m.

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**Institutional Biosafety Committee
Meeting Minutes
April 28th, 2005**

*Need room
connection P&F*

Meeting held: NDSU Memorial Union, ~~Badlands~~ Room

Members present: D. Beryhill, C. Logue, W. Dai, L. Reynolds, P. Freeman, D. Doetkott, R. Roehrdanz, J. Weiland,

Members absent: D. Jensen, G. Secor, K. Kooren, V. Kettner, J. Sheng

Guest present: None

David Berryhill, Chair, called the meeting to order at 10:00 a.m.

OLD BUSINESS: _____

- The Chair welcomed all members.
- The chair called for any changes or additions to the minutes of the February 10th 2005 meeting. A motion (Reynolds/Logue) was made to approve the minutes and passed unanimously.

NEW BUSINESS: _____

Review of New Protocols:

"Assessment of GRP78 levels and identification of altered genes in various kinds of cancer patients" Satadal Chatterjee, Pharmaceutical Sciences, Protocol

EXEMPT (human blood and tissue)- Protocol # B05019

A motion was made to accept the protocol (Reynolds/Logue), Biosafety level 2 is to be used for this project. The committee requested that the Director check on signage for the rooms listed on the protocol. Motion carried unanimously.

"CLIA waived test training session" Ross Wilhelm, Pharmacy Practice,

HUMAN BLOOD AND TISSUE - Protocol # B05020

The protocol was deferred for a later meeting, Biosafety level 2 is to be used for this project. A new submission of the protocol was asked with a better description of the project and training.

“Pathogenesis and resistance of Salmonells and Campylobacter” Catherine Logue, Vet and Micro Sciences,

INFECTIOUS AGENTS - Protocol # B05021

A motion was made to accept the protocol (Doetskott/Roehrdanz), Biosafety level 2 is to be used for this project. The PI gave a quick overview of the project. The PI clarified the processes in the protocol. Records were requested for training of one person listed on the protocol. Logue recused herself during voting. Motion carried unanimously.

“Food Safety Risk Assessment” Catherine Logue, Vet and Micro Sciences,

INFECTIOUS AGENTS - Protocol # B05022

A motion was made to accept the protocol (Doetskott/Roehrdanz), Biosafety level 2 is to be used for this project. The PI gave a quick overview of the project. The PI clarified the difference between the two protocols and gave some more background on the electronic noise and sensors. Logue recused herself during voting. Motion carried unanimously.

“Food Safety Risk Assessment” Catherine Logue, Vet and Micro Sciences,

INFECTIOUS AGENTS - Protocol # B05023

A motion was made to accept the protocol (Weiland/Dai), Biosafety level 2 is to be used for this project. The PI gave a quick overview of the project. Logue recused herself during voting. Motion carried unanimously.

“Drought tolerance of manitol-accumulating wheat: Mechanisms and agronomic evaluation” Mohamed Mergoum, Plant Sciences,

NON - EXEMPT - Protocol # B05024

A motion was made to accept the protocol (Weiland/Logue), Biosafety level 1 is to be used for this project. The committee wanted to know the protein expressed, who are the collaborators in the USDA areas, and plasmid vectors. Motion carried unanimously.

“Enhanced scab resistance in wheat germplasm by transformation” Mohamed Mergoum, Plant Sciences,

NON - EXEMPT - Protocol # B05025

A motion was made to accept the protocol (Doetskott/Dai), Biosafety level 1 is to be used for this project. The committee wanted to know the protein expressed, who are the collaborators in the USDA areas, and plasmid vectors. Motion carried unanimously.

Change in Protocol:

None at this time

DISCUSSION ITEMS: _____

- Call for discussion items - None

RECENT POSTINGS TO IBC LISTERV: _____

- None at this time

ANNOUNCEMENTS: _____

- Next meeting date, to be announced

Meeting Adjourned 10:30 a.m.

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Institutional Biosafety Committee

Office of the Vice President for Research, Creative Activities & Technology Transfer

1735 NDSU Research Park Drive

P.O. Box 5756

Fargo, ND 58105-5756

**Institutional Biosafety Committee
Meeting Minutes
June 23rd, 2005**

Meeting held: NDSU Memorial Union, Badlands Room

Members present: D. Beryhill, W. Dai, P. Freeman, D. Jensen, G. Secor, , J. Weiland, K. Kooren, D. Doetkott, R. Roehrdanz; C. Logue (at 10:15).

Members absent: L. Reynolds, R. Roehrdanz, J. Sheng, V. Kettner.

Guests present: Jolean Pederson (at 10:10), CeCe Rohwedder.

David Berryhill, Chair, called the meeting to order at 10:02 a.m.

OLD BUSINESS: _____

- The Chair welcomed all members.
- The chair called for any changes or additions to the minutes of the April 28th 2005 meeting. A motion (Secor/Jensen) was made to approve the minutes and passed unanimously.

NEW BUSINESS: _____

Review of New Protocols:

"A genetic engineering approach to solve chlorosis problems of trees" W. David Dai, Plant Sciences,

NON-EXEMPT - Protocol # B05026

A motion was made to accept this Biosafety Level 1 protocol (Jensen/Kooren). Dai recused himself during voting. Motion carried unanimously.

"Event selection, efficiency, and agronomic performance of transgenic wheat genotypes with TriR and Tri101 Fusarium head blight resistance genes" Mohamed Mergoum, Plant Sciences,

NON EXEMPT - Protocol # B05027

A motion was made to accept this Biosafety Level 1 protocol (Secor/Doetkott). It was noted that there is an APHIS permit for this protocol and that the genes should be listed,

A motion was made to accept the protocol (Weiland/Kooren), It was indicated that the "yes" responses in Sections IV and V show as such because that is the default answer; they should be "no." Motion carried unanimously.

Protocols reviewed and determined not to be within scope of review:

"Role of compensatory growth in epigenetic control of mammary gene expression and lactation" Chung Park, Animal & Range Sciences

Protocol # B05033

The Director reviewed this protocol, discussed it with the technician and determined that it did not meet definition of rDNA. The board agreed. Such submissions will be handled this manner in the future.

Change in Protocol:

None at this time

Updates to Non-Exempt Protocols:

"Transformation of Barley and Durum with Antifungal and Antioxin Genes" Lynn Dahlen, USDA – NCSL, Protocol # BO2054

A motion was made to accept this protocol update (Secor/Kooren). The investigator indicated that she had not received an update form. That is because the process is new and the review due dates are now coming up for the first time. The system is in place now to conduct reviews, and a simple form will be used.

DISCUSSION ITEMS: _____

- Non Exempt Protocols: The Director stated that he's been in communication with the Office of Biotechnology re APHIS permits. In the past protocols with APHIS permits have been classified as exempt, but they should have been non-exempt and should be re-reviewed periodically. A listing of current exempt protocols and those which should have been classified as non-exempt was distributed and reviewed. It was mentioned that some crops are exempt from APHIS permits; even if they are exempt from USDA, however, they are not exempt from IBC. Secor will and the Director will seek out and discuss additional information on USDA APHIS exemptions and permits.
- Letters to the Editor, Applied Biosafety: these were reviewed.
- Notices for Exempt Protocols: protocol review notices will be sent shortly for protocols approved during the first half of the calendar year as well as for non-exempt protocols.
- Call for Discussion Items: A listing of scheduled meetings for Fiscal Year 2006 was distributed. It should be noted that the date for the April 2006 meeting should

IBC PROJECTS RECLASSIFIED TO NON-EXEMPT [AS OF 080205]

PROTOCOL NUMBER	PI NAME	PROTOCOL TITLE	DATE RECLASSIFIED	STATUS
B02044	Mehlhoff, Randy	Transgenic Wheat (HRSW) Research	071905	Closed 072905
B02046	Howatt, Kirk	Annual Weed Control in Small Grains	071805	Closed 072905
B02047	Howatt, Kirk	Weed Shifts in Roundup Ready Cropping System	071805	Closed 072905
B02048	Helms, Ted	Soybean Improvement	071805	
B02050	Lukach, John	Roundup Ready Wheat Field Evaluation	071805	
B02055	Mergoum, Mohamed	Developing Roundup-Ready Spring Wheat	071905	Closed 072705
B03015	Howatt, Kirk	Agronomic Evaluation of Glyphosate-Resistant Wheat	071805	Closed 072905
B03016	Mergoum, Mohamed	Development of Glyphosate-Resistant HRSW Wheat	071905	Closed 072705
B03018	Howatt, Kirk	Evaluation of Glyphosate-Resistant Alfalfa	071805	Still active
B04024	Howatt, Kirk	Evaluation of Glyphosate-Resistant Wheat	071805	Closed 072905

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**Institutional Biosafety Committee
Meeting Minutes
June 23rd, 2005**

Meeting held: NDSU Memorial Union, Badlands Room

Members present: D. Beryhill, W. Dai, P. Freeman, D. Jensen, G. Secor, , J. Weiland, K. Kooren, D. Doetskott; C. Logue (at 10:15).

Members absent: L. Reynolds, R. Roehrdanz, J. Sheng, V. Kettner.

Guests present: Jolean Pederson (at 10:10), CeCe Rohwedder.

David Berryhill, Chair, called the meeting to order at 10:02 a.m.

OLD BUSINESS: _____

- The Chair welcomed all members.
- The chair called for any changes or additions to the minutes of the April 28th 2005 meeting. A motion (Secor/Jensen) was made to approve the minutes and passed unanimously.

NEW BUSINESS: _____

Review of New Protocols:

“A genetic engineering approach to solve chlorosis problems of trees” W. David Dai, Plant Sciences,

NON-EXEMPT - Protocol # B05026

A motion was made to accept this Biosafety Level 1 protocol (Jensen/Kooren). Dai recused himself during voting. Motion carried unanimously.

“Event selection, efficiency, and agronomic performance of transgenic wheat genotypes with TriR and Tri101 Fusarium head blight resistance genes” Mohamed Mergoum, Plant Sciences,

NON EXEMPT - Protocol # B05027

A motion was made to accept this Biosafety Level 1 protocol (Secor/Doetskott). It was noted that there is an APHIS permit for this protocol and that the genes should be listed, and there was a question as to whether we need to know which protein will be expressed. Motion carried unanimously.

“Prevalence and Antimicrobial Resistance Profiles of Campylobacter spp., Escherichia coli and Salmonella Serovars in Retail Turkey Meat Products from US Midwestern Retail Outlets” Margaret Khaita, Vet and Micro Sciences, INFECTIOUS AGENTS - Protocol # B05028

Biosafety level 2 is to be used for this project. The personnel needing training received such after the protocol was submitted. Doetskott indicated that the “yes” responses in Sections IV and V show as such because that is the default answer; they should be “no.” A motion was made to accept the protocol as amended (Jensen/Weiland). Doetskott recused herself during voting. Motion carried unanimously.

J. Pederson and C. Logue joined the meeting at this time.

“Investigation of presence of enteric pathogens (E. coli 0157:H7, Salmonella and Campylobacter) and past exposure to BVDV, Neospora caninum and Johnes Disease in a bison herd” Margaret Khaita, Vet and Micro Sciences, INFECTIOUS AGENTS - Protocol # B05029

Biosafety level 2 is to be used for this project. Doetskott indicated that the “yes” responses in Sections IV and V show as such because that is the default answer; they should be “no.” A motion was made to accept the protocol as amended (Jensen/Kooren). Doetskott recused herself during voting. Motion carried unanimously.

“Incidence of ecology or macrolide resistance Campylobacter in chickens and turkeys” Catherine Logue, Vet and Micro Sciences, INFECTIOUS AGENTS - Protocol # B05030

Biosafety level 2 is to be used for this project. The funding for this project is about to arrive. It was indicated that the “yes” responses in Sections IV and V show as such because that is the default answer; they should be “no.” The approval date will be the earliest approval date shown on the paperwork Logue sends to Iowa. A motion was made to accept the protocol as amended (Jensen/Dai). Logue recused herself during voting. Motion carried unanimously.

“Regulation of onitine decarboxylase gene expression” Robert Sparks, Chemistry and Molecular Biology, EXEMPT - Protocol # B05031

A motion was made to accept the protocol (Doetskott/Secor), Biosafety level 1 is to be used for this project. The committee requested that all proteins be added in the section describing proteins to be expressed, and to clarify the location of the storage units mentioned in Section VII. Motion carried unanimously.

“Prevalence and Antimicrobial Resistance Profiles of Campylobacter spp., Escherichia coli and Salmonella Serovars on Retail Bison Meat Products from US Midwestern Retail Outlets” Margaret Khaita, Veterinary & Microbiological Sciences INFECTIOUS AGENTS - Protocol # B05034

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**Institutional Biosafety Committee
Meeting Minutes
October 13th, 2005**

Meeting held: NDSU Memorial Union, Crest Room

Members present: D. Beryhill, W. Dai, P. Freeman, D. Jensen, C. Logue, J. Weiland, K. Kooren, J. Sheng; D. Doetkott (at 10:12).

Members absent: L. Reynolds, R. Roehrdanz, V. Kettner, Mike Borr.

Guests present: CeCe Rohwedder.

David Berryhill, Chair, called the meeting to order at 10:05 a.m.

OLD BUSINESS: _____

- The Chair welcomed all members.
- The Chair called for any changes or additions to the minutes of the June 23rd 2005 meeting; there being none, the minutes were approved as distributed.

NEW BUSINESS: _____

Review of New Protocols:

"Map-based Cloning of Dormancy QTLs from Weedy Rice" Michael Foley, USDA ARS, Protocol # B06001

A motion was made to accept this protocol (Wieland/Logue). It was noted that everything in paragraphs 2 and 3 of the protocol will take place at the University of Arkansas; the NDSU researchers will only receive and test seed of transgenic plants. It was agreed that the protocol will be classified as non-exempt. [Dawn Doetkott arrived at this time, at 10:12am.] The PI will be directed to ensure that the dormancy tests can be performed in areas from which no pollen can escape and will be informed that an APHIS permit is required in order for the seed to be transferred across state lines. Motion carried unanimously, with the specified requirements.

Protocols reviewed and approved via the Designated Reviewer process

The Director stated that new protocols which are not non-exempt are now being approved outside the meetings, as long as no committee member requests review by the entire committee. Protocols thus approved, as well as protocol updates, will be included in the agenda for the next committee meeting, for the members' information. The Director added that comments on protocols should be e-mailed to the Chair, who is the Designated Reviewer, and copied to the Director, so that recommendations and suggestions for changes may be taken into consideration.

Protocols reviewed and determined not to be within scope of review:

None at this time

Change in Protocol:

None at this time

Progress Reports:

- o **"Weed Shifts in Roundup Ready Cropping System"** Kirk Howatt, Plant Sciences, Protocol #B02047, terminated by the PI on July 29, 2005
- o **"Topical Gene Delivery"** Jagdish Singh, Pharmaceutical Sciences, Protocol #B02056, terminated by the PI on June 30, 2005

No narratives from the PIs were received on these protocols, and this will be requested of them, so that they may be part of the IBC records; these narratives could be parts of reports that the PIs have already submitted to other agencies. Such narratives will be needed for all non-exempt protocols, however, NIH guidelines are not specific on what should be included in the three-year reports on non-exempt protocols.

DISCUSSION ITEMS: _____

- Reclassified Protocols: A lot of the protocols which were recently reclassified to non-exempt had APHIS permits.
- OBA visits: Planned visits by the Office of Biotechnology Activities to various IBCs will be taking place in the next couple of years. Since the only North Dakota IBCs on record are those at NDSU and UND, it is not clear if the USDA office will also be visited, as it may not be under OBA jurisdiction. The Director will notify the local USDA office director, Bill Kemp, as well as Richard Roehrdanz and John Wieland, of the upcoming visit to the NDSU IBC, so they may be available, should they also receive an OBA visit.

- Policy Manual update: the Director has begun updating the IBC web site, providing links to appropriate web sites. He distributed copies of the new site's home page, pointing out that some areas may still be updated and that the web site template will be changed to that of the current IRB web site. C. Logue informed the committee that new requirements for shipping of hazardous materials include security training, and that the training CD may be purchased for use. Her department now has personnel trained in compliance with the new requirements. She will e-mail the information for acquiring the training CD to the Director and to the IBC listserv.
- Listserv: the Director asked members to inform him if they have problems sending emails via the IBC listserv.
- Registration with the Office of Biosafety: the Director announced that he has re-registered with the Office of Biosafety, which is effective for another year.

RECENT POSTINGS TO IBC LISTERV: _____

- None at this time

ANNOUNCEMENTS: _____

- Next meeting date: December 8, 2005, 10:00 – 11:00am, Crest Room, Memorial Union.

Meeting Adjourned 10:32 a.m.

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May 17, 2006

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

RE: Request for NDSU Institutional Biosafety Committee Meeting Minutes
Mail Returned

Dear Mr. Hammond:

Enclosed you will find our response to your request of March 15, 2006, which was mailed from NDSU certified mail on April 26. We received our mailing back as undeliverable. Enclosed is the envelope showing the material was mailed prior to your request date of April 28.

Sincerely,



Lois Christianson, CLA
Legal Assistant

Enc.

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