Office of Research Safety

Northwestern University NG-71 Technological Institute 2145 Sheridan Road Evanston, Illinois 60208-3121

Phone 847-491-5581 fax 847-467-2797 www.northwestern.edu/research-safety



OTHERS ALREADY ...

April 14, 2006

The Sunshine Project PO Box 41987 Austin, TX 78704

Dear Sir or Madam,

Pursuant to your request and NIH Guidelines, enclosed are copies of the minutes of the last four meetings of the Northwestern University Institutional Biosafety Committee.

Sincerely,

L. Todd Leasia, Director

encl. Recombinant DNA Safety Committee Meeting, April 14, 2005
Recombinant DNA Safety Committee Meeting, Nov 4, 2005
Recombinant DNA Safety Committee Meeting, January 11, 2006
Recombinant DNA Safety Committee Meeting, April 6, 2006

## **Recombinant DNA Safety Committee**

Meeting Minutes April 14, 2005

**Members in Attendance:** William Schnaper (Chair), Fred Martinson (Biological Safety Officer), David McPherson, Richard Burt, Alexandra Song (Community Member), Stephen Levin (Ex-Officio), Todd Leasia (Ex-Officio), Susanne Wagner (visitor).

**Members Absent:** Nicholas Cianciotto, Robert Lamb, Susan Fox (Technical Staff Representative), Mary Cipriano (Community Member), Geoff Kansas.

The meeting was called to order by the chair at 2:50 p.m. in Ward B106, Northwestern University.

#### 1. Introductions

The committee members briefly introduced themselves.

## 2. Approval of RDSC Meeting Minutes

Discussion: A draft of the minutes from the April 24, 2004 RDSC meeting was circulated electronically prior to the meeting. Motion: Approve the minutes as distributed. The motion was seconded. A vote was called and passed unanimously. The Chair signed the minutes.

#### 3. Pre-review Process

Discussion: The process for allowing the BSO to pre-review RDNA registrations and grant full approval for exempt work was formalized. Motion: The BSO is authorized to pre-review all RDNA registrations and grant full approval to category III-F exempt work. The motion was seconded. A vote was called and passed unanimously.

## 4. ORS Database Update

Susanne Wagner informed the committee of progress in developing a new Office of Research Safety database for handling RDNA registrations.

#### **REVIEW OF PROTOCOLS**

#### Protocol 2004-0015

Understanding the genetic contributions involved in pancreatic cancer development and evaluating therapies against this disease.

Non-exempt work is proposed (under III-D4)

The committee approved this protocol.

#### Protocol 2004-0022

Investigations of agents that modulate angiogenesis Proposes exempt and non-exempt experiments (III-D-4) The committee approved this protocol with a minor modification. Murine models of multiple sclerosis Proposing exempt work (IIID-3, III-D4, III-E3) Appropriate safety measures are documented in the protocol.

#### Protocol 2004-0041

Development of non-viral vectors for gene therapy Proposing exempt work and non-exempt work (III-D4, III-E1) Appropriate safety measures are documented in the protocol. The committee approved this protocol.

#### Protocol 2004-0036

Mechanisms of plasticity at the mossy fiber synapse Mon-exempt work is proposed (III-E3)
Appropriate safety measures are documented in the protocol.
The committee approved this protocol.

#### Protocol 2004-0031

Structure and function of the influenza virus genome and structure and expression of the paramyxovirus SV5 genome
Proposes exempt and non-exempt work (III-D1, III-D2)
Appropriate safety measures are documented in the protocol.
The committee approved this protocol.

#### Protocol 2004-0030

Studies of signal transduction and gene regulation Proposing exempt work and non-exempt work (III-D-4) Appropriate safety measures are documented in the protocol. The committee approved this protocol.

## Protocol 2004-0029

DNA sequencing by ELFSE on microfluidic devices Exempt work is proposed (III-F)
Appropriate safety measures are documented in the protocol.
The committee approved this protocol.

## Protocol 2004-0028

Inhibition of neointimal hyperplasia by nitric oxide Proposing exempt work and non-exempt work (III-D-4) Appropriate safety measures are documented in the protocol. The committee approved this protocol.

#### Protocol 2004-0027

Protocol 2004-0025
Protein unfolding in the cell
Exempt work is proposed (III-F)
Appropriate safety measures are documented in the protocol.
The committee approved this protocol.

10/4/05 Date

The committee approved this protocol

Protocol 2004-0042

Gene regulation of proteinuria

Proposing exempt work and non-exempt work (III-D-4)

The committee approved this protocol Appropriate safety measures are documented in the protocol.

Protocol 2004-0044

Otolith vestibule-ocular reflex

Non-exempt work is proposed (III-E3)

The committee approved this protocol. Appropriate safety measures are documented in the protocol.

Protocol 2004-0051

Establish C. elegans as a model organism for prion research

Exempt work is proposed (III-F)

The committee approved this protocol.

Protocol 2004-0052

Exempt work is proposed (III-F) Common transcription factors regulate the CYBB and NCF2 genes

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

Protocol 2004-0053

Exempt work is proposed (III-F) Synaptic transmission and calcium signaling

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

Protocol 2004-0056

nucleolus The perinucleolar compartment and malignant transformation structure and function of the

Exempt work is proposed (III-F)

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

William Schnaper (Chair)

There was no further business, a motion was made, seconded, and passed to adjourn the

meeting at 4:15 p.m.

## **Recombinant DNA Safety Committee**

Meeting Minutes November 4, 2005

**Members in Attendance:** William Schnaper (Chair), Fred Martinson (Biological Safety Officer), Susan Fox (Technical Staff Representative), Richard Burt, Geoff Kansas, Mary Cipriano (Community Member), Stephen Levin (Ex-Officio).

Members Absent: David McPherson, Nicholas Cianciotto, Robert Lamb, Alexandra Song (Community Member).

The meeting was called to order by the chair at 10:00 a.m.

1. Approval of RDSC Meeting Minutes

Discussion: A draft of the minutes from the April 14, 2005 RDSC meeting was circulated electronically prior to the meeting. Motion: Approve the minutes as distributed. The motion was seconded. A vote was called and passed unanimously. The Chair signed the minutes.

#### **REVIEW OF PROTOCOLS**

#### Protocol 2004-0048

Entry of herpes simplex virus into cells and cell-cell fusion Exempt and Non-exempt work is proposed (under III-D4 and III-E1) Appropriate safety measures are documented in the protocol. The committee approved this protocol.

#### Protocol 2004-0049

Tetrahymena molecular genetics/modifier genes in the mouse Exempt and Non-exempt work is proposed (under III-D4) Appropriate safety measures are documented in the protocol. The committee approved this protocol.

#### Protocol 2004-0050

Hyperexcitability of SOD-1 motoneurons and its genesis by voltage-sensitive currents Non-exempt work is proposed (under III-D4 and III-E3) Appropriate safety measures are documented in the protocol. The committee approved this protocol.

#### Protocol 2005-0029

Bladder Tissue Engineering Through Nanotechnology Non-exempt work is proposed (under III-C) Appropriate safety measures are documented in the protocol IRB and RAC approval was documented. The committee approved this protocol.

African Schnaper (Chair)

There was no further business, a motion was made, seconded, and passed to adjourn the meeting at 10:30 a.m.

## January 11, 2006 Meeting Minutes Recombinant DNA Safety Committee

Lamb, Mary Cipriano (Community Member). Officer), Susan Fox (Technical Staff Representative), David McPherson, Geoff Kansas, Robert Members in Attendance: William Schnaper (Chair), Fred Martinson (Biological Safety

Members Absent: Richard Burt, Nicholas Cianciotto, Alexandra Song (Community Member).

The meeting was called to order by the chair at 9:30 a.m.

was seconded. A vote was called and passed unanimously. The Chair signed the minutes. electronically prior to the meeting. Motion: Approve the minutes as distributed. The motion Discussion: A draft of the minutes from the November 4, 2005 RDSC meeting was circulated 1. Approval of RDSC Meeting Minutes

## REVIEW OF PROTOCOLS

2

The committee approved this protocol. Appropriate safety measures are documented in the protocol Exempt work is proposed (under III-D2) Mechanism of beta-catenin targeting to adhesion or signaling complexes Protocol 2004-0065

Appropriate safety measures are documented in the protocol Exempt work is proposed (under III-F6) Cellular mechanism of action of alcohol Protocol 2004-0080

The committee approved this protocol.

Protocol 2004-0081

Appropriate safety measures are documented in the protocol Exempt work is proposed (under III-E3) Olfactory neuron apoptosis: role of the Bcl-2 proteins

The committee approved this protocol.

Protocol 2004-0082

The committee approved this protocol. Exempt work is proposed (under III-F1, II-F3, and III-F6) The pathogenesis of Kawasaki disease

Exempt work is proposed (under III-F6) The roles of PBP and PRIP in breast cancer Protocol 2004-0083

The committee approved this protocol.

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org

Protocol 2004-0084

Exempt work is proposed (under III-F2 and III-F4) The role of airway epithelial cells in asthma

The committee approved this protocol.

Protocol 2005-0105

The committee approved this protocol. IRB and RAC approval was documented. Appropriate safety measures are documented in the protocol Non-exempt work is proposed (under III-C) arthritis subjects with and without concurrent TNF-alpha antagonists recombinant adeno-associated vector containing the TNFR:Fc fusion gene, in inflammatory A phase 1 dose escalation study of repeat intra-articular administration of tgAAC94, a

meeting at 10:00 a.m. There was no further business, a motion was made, seconded, and passed to adjourn the

9 /06/ c6 Milliam Schnaper (Chair)

### April 6, 2006 Meeting Minutes Recombinant DNA Safety Committee

Cianciotto, Robert Lamb, Mary Cipriano (Community Member). Officer), Susan Fox (Technical Staff Representative), Richard Burt, Geoff Kansas, Nicholas Members in Attendance: William Schnaper (Chair), Fred Martinson (Biological Safety

Members Absent: David McPherson, Alexandra Song (Community Member).

The meeting was called to order by the chair at 1:00 p.m.

was seconded. A vote was called and passed unanimously. The Chair signed the minutes. electronically prior to the meeting. Motion: Approve the minutes as distributed. The motion Discussion: A draft of the minutes from the January 11, 2006 RDSC meeting was circulated 1. Approval of RDSC Meeting Minutes

### REVIEW OF PROTOCOLS

Exempt and non-exempt work is proposed (under III-D4 and III-E3) Protocol 2004-0037

The committee approved this protocol. Appropriate safety measures are documented in the protocol Regulation of synaptic plasticity

The committee approved this protocol. Appropriate safety measures are documented in the protocol Exempt work is proposed (under III-F4) Anti-inflammatory effects of arterial elastic lamiane Protocol 2004-0038

Inhibition of neointimal hyperplasia by nitric oxide Protocol 2004-0046

The committee approved this protocol. Appropriate safety measures are documented in the protocol Exempt and non-exempt work is proposed (under III-D1 and III-D4)

Exempt work is proposed (under III-E3) Placental hormones and the control of hematopoiesis Protocol 2004-0047

Appropriate safety measures are documented in the protocol

The committee approved this protocol.

Protocol 2004-0054

Non-exempt work is proposed (under III-D4) Lrp5 mediated osteoblastogenesis in the aortic valve

The committee approved this protocol. Appropriate safety measures are documented in the protocol

Protocol 2004-0059

Appropriate safety measures are documented in the protocol Exempt and non-exempt work is proposed (under III-D4 and III-E3) Role of gangliosides on cell motility/ role of ganglioside on uPAR signaling

The committee approved this protocol.

Protocol 2004-0086

Cytokine signaling

Exempt work is proposed (under III-E1)

Appropriate safety measures are documented in the protocol

The committee approved this protocol.

meeting at 1:35 p.m. There was no further business, a motion was made, seconded, and passed to adjourn the

#### Office of Research Safety

Northwestern University B-106 Ward Building, W-223 303 East Chicago Avenue Chicago, Illinois 60611-3008



History dates | Convert

May 17, 2004

Mr. Edward Hammond The Sunshine Project 101 West 6<sup>th</sup> Street, Suite 607 Austin, TX 78701

Dear Mr. Hammond,

Pursuant to your request of March 26, 2004, the minutes of the last two meetings of the Northwestern University Institutional Biosafety Committee at which a protocol was reviewed and approved, rejected, or upon which action was deferred are attached.

Sincerely,

L. Todd Leasia

Director

Enclosures: March 30, 2004 minutes

April 29, 2004 minutes

#### RECOMBINANT DNA SAFETY COMMITTEE MELI'ING March 30th 2004

Members Present: William Schnaper (Chair), Kathryn Harris (Biological Safety Officer), Catherine Counard, Mary Cipriano, Susan Fox, Todd Leasia (Ex-Officio), Susanne Wagner (visitor).

Members Absent: Nicholas Cianciotto, Geoff Kansas

- 1. The meeting was called to order at 2.10 p.m.
- 2. The committee voted unanimously to approve the minutes from Feb 23<sup>rd</sup> 2004 Meeting. The Chair signed the minutes.
- 3. The committee provided comments on, and minor edits to, the draft of the new registration. The comments will be incorporated by the Biological Safety Officer to finalize the registration document. The committee would like to review several registrations on the new form to iron out potential problems before final approval of the document.
- 4. The majority of the committee wish to continue to receive paper copies of registrations for review. Mary Cipriano would prefer electronic versions.
- 5. Todd Leasia received a 2<sup>nd</sup> letter from the Sunshine Project requesting copies of two sets of minutes from meetings where protocols were assessed. Copies will be provided.
- 6. The Chair discussed the ACUC protocol approval process with the ACUC chair Bill Karpus, Dr. Karpus confirmed that approval for the use of transgenic animals will be granted only after RDSC approval is obtained.

#### Review of protocols

#### Procotol 2004-0001

To understand nuclear control of the respiratory chain. Both exempt and non-exempt work is proposed (under section III-E-1) Viral vectors are to be used (adenoviral and ecotropic lentivirus) Appropriate safety measures are documented in the protocol. The committee approved this protocol

#### Protocol 2004-0002

Role of MMP2 in the formation of abdominal aortic aneurysms Both exempt and non-exempt work is proposed (under section III-D-4-a) No viral vectors are to be used. Appropriate safety measures are documented in the protocol. The committee asked for minor clarification of question 16 committee approved this protocol

#### Protocol 2004-0003

Functions of molecular motor tails This protocol is exempt from the NIH guidelines Appropriate safety measures are documented in the protocol. The committee approved this protocol

#### Protocol 2004-0004

Regulation of signal transduction in mesangial and endothelial cells The committee returned this protocol to the PI for additional information (NIH category not identified).

There was no other business and the committee adjourned at 3.15 p.m.

## RECOMBINANT DNA SAFETY COMMITTEE MEETING April 29th 2004

Members Present: William Schnaper (Chair), Kathryn Harris (Biological Safety Officer), Mary Cipriano, Susan Fox, Geoff Kansas, Bob Lamb.

Members Absent: Catherine Counard, Todd Leasia (Ex-Officio), Nicholas Cianciotto

- 1. The meeting was called to order at 2.00 p.m.
- 2. The committee voted unanimously to approve the minutes from March meeting. The Chair signed the minutes.
- 3. The committee discussed the confusion over the correct NIH sections for use of transgenic animals. The Biological Safety Officer will put together a guide for investigators
- 4. Todd Leasia will send the last two sets of minutes from meetings where protocols were assessed to the Sunshine project as per their request
- 5. The committee approved the new program documents (with minor edits to the registration form) which will now be sent to the Vice President's Office for final approval.

#### **REVIEW OF PROTOCOLS**

#### Protocol 2004-0004

Effect of TGF-beta on mesangial cell functions Proposing non-exempt experiments (III-D-4) Appropriate safety measures are documented in the protocol. The committee approved this protocol

#### Protocol 2004-0005

No title entered

Proposing exempt work and non-exempt work (III-D-4)

Appropriate safety measures are documented in the protocol.

The committee approved this protocol after the project title is obtained.

#### Protocol 2004-0006

Molecular physiology of Hepatic Transport Non-exempt work proposed (III-D-4) Appropriate safety measures are documented in the protocol. The committee approved this protocol pending minor modifications.

#### Protocol 2004-0007

Reproductive Biochemistry of LDH-X
Exempt and non-exempt work is proposed (III-D-4)
Appropriate safety measures are documented in the protocol.
The committee approved this protocol after the PI signs the form.

#### Protocol 2004-0008

Study of the effect of proliferating cell nuclear antigen overexpression. Proposes exempt and non-exempt experiments (III-D-4)

The committee approved this protocol pending minor modifications.

#### Protocol 2004-0009

Master Immunization Protocol of Monoclonal Antibody Facility

Exempt work only is proposed.

The committee returned this protocol to the investigator for clarification on several points

#### Protocol 2004-0010

Molecular studies of leukocyte traffic and plasma cell development.

Proposes exempt and non-exempt work (III-E-3 and III-D-4)

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

#### Protocol 2004-0011

Studies of the glomerular capillary wall: normal and pathologic and pathogenesis of diabetic nephropathy

Exempt and non-exempt work is proposed (III-D-4)

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

#### Protocol 2004-0012

Pathogenic mechanisms of TMEV-induced demyelination

Exempt and non-exempt work is proposed (III-D and III-E)

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

#### Protocol 2004-0013

Cytokine signaling

Exempt and non-exempt work is proposed (III-E-1)

The committee approved this protocol pending modifications.

#### Protocol 2004-00014

Neurological deficits due to toxic ABeta oligomers

Exempt and non-exempt work is proposed (III-D-4)

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

#### Protocol 2004-0015

Understanding the genetic contributions involved in pancreatic cancer development and evaluating therapies against this disease.

Non-exempt work is proposed (under III-D-4)

The committee rejected this protocol as it was not submitted by an investigator with a faculty appointment.

#### Protocol 2004-0016

Mechanotransduction of eosinophil function

Exempt and non-exempt work is proposed (III-D-4)

Appropriate safety measures are documented in the protocol.

The committee approved this protocol.

There was no other business and the committee adjourned at 3.30 p.m.

William Schnaper (Chair)

5/4/04 Date

#### Office of Research Safety

Northwestern University B-106 Ward Building, W-223 303 East Chicago Avenue Chicago, Illinois 60611-3008



February 24, 2004

The Sunshine Project 101 West 6th Street, Suite 607 Austin, TX 78701

Dear Sir or Madam,

no protect verice le Pursuant to your request and NIH Guidelines, enclosed are copies of the Minutes of the two most recent meetings of the Northwestern University Institutional Biosafety Committee.

Sincerely,

L. Todd Leasia, Director

Recombinant DNA Safety Committee Meeting, July 7, 2003 encl:

Recombinant DNA Safety Committee Meeting, January 19, 2004

Wamp to

# SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org RECOMBINANT DNA SAFETY COMMITTEE MEETING

## January 19th 2004

Members Present: William Schnaper (Chair), Kathryn Harris, Geoff Kansas, Nicholas Cianciotto, Mary Cipriano, Catherine Counard, Susan Fox, Todd Leasia (Ex-Officio), Susanne Wagner (visitor).

Members Absent: None

- 1. The meeting was called to order at 2.10 p.m.
- 2. Approval of minutes: There was no official meeting on July 7th 2003, however the committee noted the informal notes from that meeting.
- 3. Program statistics and reports: A report on the current status of the program was provided for committee and the committee reviewed the program statistics. For FY03 there was 100% compliance by registered Principal Investigators for the submission of Annual Status Reports.
- 4. The need to integrate the use of web based forms into the registration and review process was stressed by Geoff Kanses. Todd Leasia described the timeline for possible implementation. Where possible forms will be made available in PDF format.
- 5. The committee discussed the addition of members. Two faculty should be added with at least one recruited from the Evanston campus.
- 6. The committee voted unanimously to approve the charter, annual status form and program core document with minor edits (to be made by the Biological Safety Officer) and forward them to the Vice President for Research for final approval.
- 7. The committee asked that the IRB (Lewis Smith) be contacted to verify that human studies involving recombinant DNA were evaluated by the hospital RDSC.
- 8. The committee were provided with a draft of a new registration document for review and comment. Comments will be sent to the Biological Safety Officer for incorporation. The committee will meet in mid-February to finalize and approve the document. When the new document is in use the full committee will systematically review all non-exempt registrations.
- 9. The committee discussed the value of recommending a policy linking approval of animal research protocols to compliance with regulations (NIH guidelines).

There was no other business and the committee adjourned at 4:10 p.m. William Schnaper (Chair) 2/23/0 9 Date

## RECOMBINANT DNA SAFETY COMMITTEE MEETING July 7th 2003

Members Present: Catherine Counard, Susan Fox, Geoff Kansas, Kathryn Harris and Susan Wagner (visitor)

Members Absent: Robert Lamb (chair), Mary Cipriano, and Todd Leasia (ex officio)

An official meeting was not called to order, as the chair was absent. The informal meeting began at 10:20 a.m.

#### 1. Membership:

- Recruitment for the committee currently there are only two faculty members on the
  committee and it has proved difficult to recruit. Ideas and suggestions for recruitment
  and committee composition were solicited. It was proposed that at least another two
  faculty, preferably one from each campus, should be recruited so the total serving
  would be four. This would avoid a situation where the faculty is in the minority on
  the committee.
- A discussion was made as to how often the committee is to meet and where. There is only one current member from the Chicago campus, Geoff Kansas, who kindly offered to travel to Evanston for meetings for the present time. This can be reassessed if more Chicago campus faculty are recruited. It was agreed that meetings should be held more regularly, particularly in the near future as we revamp the program.
- 2. Minutes: There were no minutes to approve.
- 3. The Biological Safety Officer introduced committee members and gave a general introduction to the program structure and program documents. The impact of new programs was discussed.
- 4. Program statistics and reports: A report on the current status of the program was provided for committee review (number of registrations, categories of registrations etc. See RDNA Status Report 2003 for full details).
- 5. Registration Activities: Five new registration applications for committee review were distributed along with approval forms.
- 6. It was noted that ORS will start synchronizing the submission of RDNA Annual Status Reports with lab inspections and the Safety Plan Annual Status Reports as per the request of many PIs.
- 7. Policy Questions for Discussion/Vote at a later date:
  - Input was solicited regarding questions for the new registration form. A list of potential items to include on the new form was distributed. The committee will ultimately review and approve a new registration form and a new annual review form.
  - The need to re-register all PIs with the new form was discussed along with the question of often PIs should be required to re-register (currently 5 years but perhaps should be more frequent).

- The charter will be reviewed by the committee for understanding of the obligations and procedures of the committee. The charter will need amending so that the committee consists of no less than seven members (currently five) and that a minimum of four of the members are faculty. The language as to what constitutes a quorum will also need amending.
- The question of whether the PI in whose lab the recombinant DNA work is taking place must sign off on the registration form was discussed. The policy statement could be worded to the effect that a recombinant DNA registration will be approved only if the investigator filing the registration has his/her own Safety Plan on file, or if the investigator under whose Safety Plan the registrant is working has countersigned the registration.

Kathryn Harris, Biological Safety officer

JULY 10TH 2003

Date

# the sunshine project

101 West 6<sup>th</sup> Street, Suite 607 Austin TX 78701 USA
Tel/Fax: +1 512 494 0545
http://www.sunshine-project.org

26 March 2004

#### **ADVISORY COMMITTEE**

Ignacio Chapela Berkeley, United States

Chee Yoke Ling Kuala Lumpur, Malaysia

Julian Perry Robinson Brighton, United Kingdom

Tewolde Berhan Gebre Egziabher Addis Ababa, Ethiopia

Christine von Weizsäcker Bonn, Germany

Mark Wheelis
Davis, United States

#### **GERMAN OFFICE**

The Sunshine Project Scheplerstrasse 78 22767 Hamburg

Tel: +49 40 431 88 001 Fax: +49 40 675 03 988

The Sunshine Project US is a 501(c)3 non-profit organization. Donations are tax-deductible.

The Sunshine Project Germany (e.V.) is a federally recognized, taxexempt association. Mr. L. Todd Leasia Office of Research Safety Northwestern University B-106 Ward Building, W-223 303 East Chicago Ave Chicago IL 60611-3008

By fax: 312-503-0547

Dear Mr. Leasia,

Thank you for your reply, dated 24 February, to the Sunshine Project's survey of Institutional Biosafety Committees.

By this letter, and pursuant to the NIH Guidelines, the Sunshine Project hereby requests the Minutes of the last two (2) meetings of the Northwestern University Institutional Biosafety Committee <u>at which a protocol was reviewed and approved, rejected, or upon which action was deferred.</u>

Our evaluation criteria in this survey are the following:

- Adequate description of protocols under consideration (35%);
- Useful detail provided of discussions of the protocols (25%);
- Scope of biosafety issues reflected in the Minutes (25%);
- Demeanor of the Institution with respect to requests (15%).

The total score each IBC receives for the above criteria may be modified (i.e. points added or subtracted) based on specific transparency items, including the presence/absence of ([un]explained) redactions, (non)identification of committee members, and bureaucratic impediments (if any) presented to public requesters.

In view of the above, I hope that you can appreciate that it is impossible for the Sunshine Project to evaluate the Northwestern University IBC because no protocol reviews appear to have occurred during the meetings of 7 July 2003 and 19 January 2004. Accordingly, I am requesting the additional Minutes.

In addition, we note that you have not responded to the question concerning select agents. I believe that it is the moral responsibility of Northwestern University to answer this question. In order to ensure the safety and security of biotechnology, the public at large deserves to be informed of the presence of select agents should they be on your campus. I invite you and your IBC to reconsider your response.

Thank you for your time and attention in this matter.

Sincerely,

**Edward Hammond**