THE UNIVERSITY OF MISSISSIPPI MEDICAL CENTER

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Edward Hammond The Sunshine Project 1920 Stuart St Berkeley CA 94703

November 8, 2006

Dear Mr. Hammond:

Enclosed are copies of minutes of IBC meetings requested by the Sunshine Project.

Please be sure future requests are sent to my attention. It was only by chance that a fax of your letter dated 12 October 2006 addressed simply to the medical center found its way to me last week.

Sincerely, IBC Chair

Steven T. Case, Ph.D.

Stewn Cie

Professor of Biochemistry and Associate Dean for Medical School Admissions University of Mississippi Medical Center 2500 North State Street Jackson, MS 39216-4505 USA

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the sunshine project

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PAGE

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University of Mississippi Medical Center 2500 North State St. Jackson MS 39216-4505

By fax: (601) 984-1501

To Whom It May Concern:

Please read this letter carefully. It pertains to important obligations of University of Mississippi Medical Center and to a federal complaint that the Sunshine Project may lodge against it. It is important that University of Mississippi Medical Center reply.

More than six months ago, the Sunshine Project requested minutes of the University of Mississippi Medical Center Institutional Biosafety Committee (IBC). Although release of the minutes is mandatory under the NIH Guidelines for Research Involving Recombinant DNA Molecules, minutes have not been received from your institution.

This letter is to reiterate the Sunshine Project's request for the University of Mississippi Medical Center IBC minutes (from 1 May 2003 through the present). If you do not provide the requested minutes by November 6th, the Sunshine Project will immediately lodge a complaint with the National Institutes of Health. This complaint could result in a loss of research funding for your institution.

The following two situations apply to some institutions receiving this letter:

Excessive Fees: Some institutions have conditioned public access to their minutes upon payment of exorbitant fees. It is our policy to pay reasonable fees for copies and postage (from a few dollars up to about \$30, depending on the volume of minutes). Higher fees constitute an impediment to public access that is not permitted by the NIH Guidelines. If copying or mailing is difficult or expensive for you, please send the requested records by e-mail.

No FOIA Requests: The NIH Guidelines do not require the Sunshine Project to file a FOIA request (state or federal) in order to obtain your IBC minutes. The NIH Guidelines do require that you make your minutes available to the public. If you wish to have your FOIA officer or another official handle the request, we do not object in principle. In such a case, forward this request to the appropriate official(s). If you continue to refuse to honor a request made under the Public Access Provisions of the NIH Guidelines, the Sunshine Project will lodge a complaint with NIH.

If you provided some of the requested minutes in response to the Sunshine Project's 2004 survey of IBCs, it is not necessary to provide a second copy. If applicable, please make note of this situation in your reply.

The Sunshine Project's permanent address is at the top of our letterhead, however, in order to expedite receipt of your response, please send your reply to this letter to:

Edward Hammond The Sunshine Project 1920 Stuart St Berkeley CA 94703

As always, the Sunshine Project is happy to receive the requested minutes by e-mail or to download them from a public URL that you provide.

Thank you for your prompt attention to this request.

Sincerely,

Edward Hammond

Minutes of Electronic Meeting May 15, 2003

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Members 1	וטוו וואע	paung.

Dr. J. Lincoln Arceneaux
Dr. Steven T. Case
Mr. William E. Coates
Dr. Donna C. Sullivan
Dr. Andrew W. Grady
Dr. Cheryl S. Hardy
Mr. Paul I. Hicock
Ms. Janet B. Mapp
Dr. Sarah Lea McGuire
Dr. Donna C. Sullivan
Dr. Rebecca J. R. Waterer
Dr. Susan E. Wellman
Dr. Kathinka White

Members not participating:
Ms. Zelma Cason

c) Updates with changes:

- 1. Minutes of the April 25, 2003 meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were approved.

None

a) New projects:

None

Hebert (2)
Hosler
Kermode
Klett
Woolverton
Clem
McKinney
Raucher (2)
Lundrigan
Meade

Minutes of the Meeting June 27, 2003

Members present:

Dr. Steven T. Case

Dr. Susan E. Wellman

Ms. Zelma Cason

Dr. Kathinka White

Dr. Andrew W. Grady

Members participating electronically:

Mr. Paul I. Hicock

Dr. Sarah Lea McGuire

Mr. William E. Coates

Dr. Rebecca J. R. Waterer

Members not present:

Dr. J. Lincoln Arceneaux

Ms. Janet B. Mapp

Dr. Cheryl S. Hardy

Dr. Donna C. Sullivan

- 1. Minutes of the May 30, 2003 meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) New projects:

none

b) Updates without changes:

Meade

Bennett

Bratton

Hebert

Woolverton

Kermode

Hines

Rockhold

c) Updates with changes

none

3. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

Investigator

Level (correction)

Hebert

BL2 (a: Correct format and expand listing of cell lines and

viruses that may be contained therein; b: clarify where Mr. Nalls will work with recombinant DNA to ascertain whether or not he will be exposed to agents that require training for

BL2).

Rengunathan

BL2 (Correct format and expand listing of cell lines and

viruses that may be contained therein)

4. Labs tentatively schedule for BL2 certification inspections were not ready in time for Mr. Coates to inspect them before this meeting.

5. Dr. Case reported on progress towards annual registration updates. He summarized Mr. Coates' report on annual laboratory inspections.

Laboratory Animal Facilities: Biosafety sign should list biohazard: Cercopithecine

herpesvirus 1(CHV-1 or Monkey B virus)

Clinical Laboratory Science: No deficiencies noted

(SH26002, SH-261)

Duhe (R-408, G-319A-1) Biosafety sign should list biohazard: Leishmania species;

human cell lines (potentially infected with viruses), and

bacculovirus vectors.

Kermode (R-413): No deficiencies noted

Woolverton (G-118): No deficiencies noted

May (N717, R717, R719): No deficiencies noted

Warren: No deficiencies noted

(N717, R717, R719, R720)

6. Dr. Grady reported on revised CDC guidelines for infection control in the healthcare environment. UMC is currently in compliance with these guidelines.

7. The presentation on the national survey of IBCs was postponed.

Minutes of the Meeting August 29, 2003

Members present:

Dr. Steven T. Case Dr. Donna C. Sullivan Mr. William E. Coates Dr.. Jean Walker

Dr. Andrew W. Grady
Dr. Cheryl S. Hardy
Dr. Sarah Lea McGuire
Dr. Rebecca J. R. Waterer
Dr. Susan E. Wellman
Dr. Kathinka White

Members not present:

Dr. J. Lincoln Arceneaux Ms. Janet B. Mapp

Mr. Paul I. Hicock

1. Minutes of the July 25, 2003 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: Hebert

Raucher

3. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

Investigator Olson Level (correction)

BL2 (joint listing of virus/cell lines; citation of CDC guidelines)

4. Mr. Coates reported on the following BL2 certification inspections; IBC action is indicated

Regunathan (G125) Inspection satisfactory pending re-inspection of biosafety cabinet recently moved from G118; IBC approved at BL2

5. Mr. Coates reported on annual unannounced inspections of BL2 and BL3 facilities. Supervisors and their departmental chairs will be notified of the outcome; those who fail wil be required to take corrective action that will be verified by Mr. Coates.

Laboratories for the following supervisors passed BL2 (or BL3 where indicated) inspection.

Lushbaugh N-533, N-528 Meade N-531, N-533

Dorman N-504 (Apparently, there is no work being done in this lab)

Sullivan N-503, N-504, N-535 Byers N-508, N-511, N-514

Lundrigan N-513, 543 C. Gomez-Sanchez R-SB11 (VA)

Flow Cytometry R-524

Lynch R-713

Laboratories for the following supervisors passed BL3 inspection.

Sullivan N-543 Byers N-543 Lundrigan N-543

Laboratories for the following supervisors failed BL2 inspection for reasons cited below.

Finley N-528	Workers could not readily find the safety manual No informed consent forms for Mei Fang and Kashonda Kelley
Zhou R-706	Biohazard sign not current (still lists Dr. King as the PI) No biosafety manual in the room
Bennett N-314	Biosafety manual not current, no informed consent statements or
Cohly L-219, 220,	Biosafety cabinet in L-219 last certified 5-28-02, was due in 5-03.

- 6. The final draft of a memo alerting UMC faculty of the need to register work with human or primate cells at BL2 was reviewed, suggestions for changes made and approved.
- 7. Dr. Case informed the IBC that under 43 CFR 73, an inspection team from the CDC was scheduled to visit UMC on September 4, 2004 in conjunction with our application for registration with the Select Agent program. Preparations have been underway for detailed scrutiny of facilities, documents and personnel involved with select agents. The outcome will be reported at or next meeting.

Minutes of the Meeting October 31, 2003

Members present:

Dr. J. Lincoln Arceneaux
Mr. Paul I. Hicock
Mr. William E. Coates
Dr. Jean Walker
Dr. Andrew W. Grady
Dr. Kathinka White
Dr. Cheryl S. Hardy

Members not present:

Dr. Steven T. Case

Ms. Janet B. Mapp

Dr. Rebecca J. R. Waterer

Dr. Sarah Lea McGuire

Dr. Susan E. Wellman

1. Minutes of the August 29, 2003 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: Gu
May

3. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

Investigator Action

Blythe Approval at BL2 pending the following corrections:

Registration Form, item 2E; change pages to 97

Standardized Plans; check liquid waste

4. Mr. Coates reported on the following BL2 certification inspections; IBC action is indicated.

Hardy Inspection of L511 was satisfactory; IBC approved BL2 certification.

5. Mr. Coates reported that the following investigators who failed an annual unannounced inspection of their BL2 facility have taken the corrective action requested by the IBC. Supervisors and their departmental chairs will be notified that their labs are now compliant for work at BL2.

Finley Zhou Bennett

6. In response to CDC guidelines Appendix H that recommend work with all human and primate cells be done at BL2, the IBC discussed whether or not to reduce the containment level for work with cell lines that the American Type Culture Collection (ATCC) recommends using at BL1. The IBC's consensus was that we must adhere to the needs/requirements of the CDC. While we can appreciate ATCC's knowledge, our regulatory burden lies with the federal government. Thoughts are that we should err on the side of caution, especially since the costs associated with

working in BL-2 environments is not appreciably greater than working in a BL-1 environment. Likewise, we are a training institution, and the potential is great for someone of lesser experience to be involved in work with the various agents in question. Working at BL-2 provides a greater level of protection/confidence for the individual supervisors and the institution. It was moved and approved that work with all human and primate cell lines must remain at BL-2.

7. Dr. C. Hardy and Mr. P. Hicock have agreed to serve as the initial reviewers for a forthcoming proposal that will involve human gene therapy. Dr. Case will make sure the IRB is aware of the need for IBC involvement.

Minutes of the Meeting December 5, 2003

Members present:

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Dr. J. Lincoln Arceneaux

Mr. Paul I. Hicock

Mr. William E. Coates

Dr., Jean Walker

Dr. Andrew W. Grady

Dr. Rebecca J. R. Waterer

Dr. Cheryl S. Hardy

Dr. Susan E. Wellman

Members not present:

Dr. Steven T. Case

Dr. Donna C. Sullivan

Ms. Janet B. Mapp

Dr. Kathinka White

Dr. Sarah Lea McGuire

1. Dr. Grady chaired the meeting.

2. Minutes of the October 31, 2003 meeting were approved.

3. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects:

Lobb

Raucher Klett

Alexander

b) Updates without changes:

Stec

Hebert

Hosler

C. Gomez-Sanchez

4. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

Investigator Action

Choi

Approved, BL2

Byers

Approved, BL3

Guo

Approved BL2, but note the following:

a) The IRB should be notified that this proposal involves about 300 cases

of archived patient samples without any indication of IRB review.

b) Standardized Plans indicate only liquid medical/infectious waste; they should be modified to include solid medical infectious waste as well.

5. Mr. Coates reported on the following BL2 certification inspections; IBC action is indicated.

Garner

Approval, BL3 (N543-1)

Olson

Approval, BL2 (G220)

Blythe No laboratory identified; inspection on hold.

- 6. There was a brief discussion of the following article: J.H. Keene Applied Biosafety 8:132-134 (2003).
- 7. The CDC/Select Agent Program submitted their written Facility Inspection Report for UMMC stemming from the September 4, 2003 site visit. Mr. Coates distributed copies of 42 CFR Part 73 Select Agents and Toxins, the reference document for the inspection. Seven deficiencies were cited; most were related to two BL-2 labs that, based on a addendum filed in late September, are no longer registered for select agents. Action has been taken to correct the remaining deficiencies and a written response was faxed to the CDC on December 5, 2003; a hard copy was mailed on December 8th.
- 8. Mr. Coates reported that on November 26, 2003, UMMC was granted "provisional approval" for registration under of 42 CFR Part 73.
- 9. The meeting was adjourned at 1:30 pm.

Minutes of the Meeting March 26, 2004

Members present:

Dr. J. Lincoln Arceneaux

Dr. Donna C. Sullivan

Mr. William E. Coates

Dr. Susan E. Wellman

Dr. Sarah Lea McGuire

Members not present:

Dr. Steven T. Case

Ms. Janet B. Mapp

Dr. Andrew W. Grady

Dr. Jean Walker

Dr. Cheryl S. Hardy

Dr. Rebecca J. R. Waterer

Mr. Paul I. Hicock

Dr. Kathinka White

- 1. Dr. Wellman chaired the meeting.
- 2. Minutes of the February 27, 2004 meeting were approved.
 - 3. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects:

none

b) Updates without changes:

Kermode

Woolverton

c) Updates with changes:

none

4. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

<u>Investigator</u> <u>Action</u>

Regunathan Approved, BL2 (pending changes) Delayed to the April Meeting Ryan

Lobert (2) Approved, BL2 (pending changes)

5. Mr. Coates reported on the following BL2 certification inspections; IBC action is indicated.

Carmicle-Davis

Approval, BL2 (room?)

Wysocki

Approved BL2 (room?)

- 6. There was a brief discussion of the following article: J.H. Keene Applied Biosafety 8:132-134 (2003).
- 7. The meeting was adjourned at 2:00 pm.

Minutes of the Meeting April 30, 2004

Members present:

Dr. Steven T. Case Dr. Andrew W. Grady Dr. J. Lincoln Arceneaux Dr. Cheryl S. Hardy

Mr. William E. Coates

Members not present:

Mr. Paul I. Hicock Dr. Jean Walker

Ms. Janet B. Mapp
Dr. Rebecca J. R. Waterer
Dr. Sarah Lea McGuire
Dr. Susan E. Wellman
Dr. Donna C. Sullivan
Dr. Kathinka White

- 1. Minutes of the March 26, 2004 meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes: Clem

Davidson Hosler

c) Updates with changes: none

3. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

Investigator Action

Ryan Approved, BL1

4. Mr. Coates reported on the following BL2 certification inspections; IBC action is indicated.

Chinchar Approval, BL2 (R512)
Choi Approval, BL2 (L505)
Hines Approval, BL2 (L311)
Norcum Approval, BL2 (G217)
Lobert Approval, BL2 (A021)

5. The meeting was adjourned at 1:45.

Minutes of the Meeting May 28, 2004

Members participating:

Dr. Steven T. Case Dr. Donna C. Sullivan Mr. William E. Coates Dr. Jean Walker

Dr. Cheryl S. Hardy Dr. Rebecca J. R. Waterer Mr. Paul I. Hicock Dr. Susan E. Wellman

Ms. Janet B. Mapp

Members not participating:

Dr. J. Lincoln Arceneaux Dr. Sarah Lea McGuire Dr. Andrew W. Grady Dr. Kathinka White

1. Minutes of the May 28, 2004 electronic meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

a) b) Updates without changes: Chinchar

Woolverton Sinning

c) Updates with changes: none

Minutes of the Meeting June 25, 2004 at 1:00 PM

Members present:

Dr. J. Lincoln Arceneaux

Mr. Paul I. Hicock

Dr. Steven T. Case

Dr. Susan E. Wellman

Dr. Andrew W. Grady

Members not present:

Mr. William E. Coates

Dr. Donna C. Sullivan

Dr. Cheryl S. Hardy

Dr. Jean Walker

Ms. Janet B. Mapp

Dr. Rebecca J. R. Waterer

Dr. Sarah Lea McGuire

1. Minutes of the May 28, 2004 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects:

Base Pair Summer Research Institute (D. Sullivan)

b) Updates without changes: Meade

Davidson

c) Updates with changes:

none

3. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

<u>Investigator</u>

Level

Lundrigan

BL3

Raucher

BL2 (with correction to Registration Form)

- 4. Report by Paul Hicock about forthcoming wet lab training conducted by the Mississippi State Department of Health for bioterrorism response. This will take place at SHRP under the supervision of Paul Hicock
- 5. The meeting was adjourned at 1:40.

Minutes of the Meeting July 30, 2004 at 1:00 PM in R136

Members present:

Dr. J. Lincoln Arceneaux
Dr. Gary Reeves
Dr. Steven T. Case
Dr. Donna C. Sullivan
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman
Mr. Joey Kellum
Dr. Rebecca J. R. Waterer

Members not present:

Mr. William E. Coates
Dr. Sarah Lea McGuire
Dr. Andrew W. Grady
Dr. Jean Walker

Mr. Paul I. Hicock

1. New members (Mr. Kellum and Dr. Reeves) were introduced.

- 2. Dr. Case noted that in keeping with trends nationwide and the renaming of UMC's "Risk Management" department to "Occupational Health and Safety", the name of the IBC will be changed from "biohazards" to "biosafety". Appropriate changes will be made to the web site and IBC forms. Files with updated forms will be emailed to the IBC; requests for any additional changes should be submitted not later than the next IBC meeting.
- 3. Minutes of the June 25, 2004 meeting were approved.
- 4. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: Miller b) Updates without changes: Gu

Hebert

Woolverton (2)

Bennett Zhou Ordway Sinning

c) Updates without changes: none

5. The following investigators were granted IBC approval of their registration at the indicated biosafety level pending corrections noted below.

<u>Investigator</u> <u>Level</u>

Bioterrorism Wet Workshop

BL2 (pending notification to the ER that

this training session would be taking place)

- 6. Dr. Wein's human gene therapy protocol was discussed in detail. It basically involves registering UMC as a new clinical site for an ongoing Phase II clinical trial for which the Southwestern Oncology Group has acquired NIH/RAC approval to use FDA-approved (#BB-IND-9718) INGN 201, a replication-deficient adenovirus construct designed to express human p53, in combination with chemoradiation therapy to treat squamous cell carcinoma of the oral cavity and oropharynx. A variety of issues were discussed including the current use of INGN 201 in ongoing Phase I, II and III clinical trails, the projected number of patients to be treated at UMC, the use of designated rooms in the OR, SICU and 3 West, storage/handling of INGN 201 in the pharmacy and training of personnel. Additional time is needed to consider submitted documents and conclude the discussion.
- 7. The meeting was adjourned at 2:12 PM.

Minutes of the Meeting August 27, 2004 at 1:00 PM in R136

Members present:

Dr. Steven T. Case Mr. Joey Kellum Mr. William E. Coates Dr. Jean Walker

Dr. Andrew W. Grady
Dr. Rebecca J. R. Waterer
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman

Members not present:

Dr. J. Lincoln Arceneaux Dr. Gary Reeves

Mr. Paul I. Hicock
Dr. Donna C. Sullivan

Dr. Sarah Lea McGuire

1. Minutes of the July 30, 2004 meeting were approved.

2. Dr. Case reported that a) annual updates are at 100% due to the diligent efforts of his assistant, Kim Eaves and b) NIH/OBA approved the 2004 IBC roster.

3. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: Wilson

b) Updates without changes: Davidson

c) Updates without changes: none

- 4. Mr. Coates reported on the BSL-2 certification inspection for Dr. Raucher and recommended approval.
- 5. Final points for Dr. Wein's human gene therapy protocol were discussed. Registration approval at BSL-2 is pending appropriate responses/actions to IBC comments (see attached email).
- 6. All IBC forms have been reviewed; requested changes will be made. Some committee members will be asked to review the final versions.
- 7. The meeting was adjourned at 1:49 PM.

Minutes of the Electronic Meeting September 24, 2004

Members participating:

Dr. Steven T. Case Dr. Sarah Lea McGuire

Dr. J. Lincoln Arceneaux Dr. Gary Reeves

Mr. William E. Coates Dr. Donna C. Sullivan

Dr. Andrew W. Grady Dr. Jean Walker

Dr. Cheryl S. Hardy
Dr. Rebecca J. R. Waterer
Mr. Paul I. Hicock
Dr. Susan E. Wellman

Mr. Joey Kellum

1. Minutes of the August 27, 2004 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes: Ordway

Hebert (2)

c) Updates without changes: none

Minutes of the Electronic Meeting October 29, 2004

Members participating:

Dr. J. Lincoln Arceneaux
Dr. Steven T. Case
Mr. Joey Kellum
Mr. William E. Coates
Dr. Andrew W. Grady
Dr. Jean Walker
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman

Members not participating:

Dr. Sarah Lea McGuire Dr. Rebecca J. R. Waterer

Dr. Donna C. Sullivan

1. Minutes of the September 24, 2004 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

a) b) Updates without changes: Drummond

Duhe Hebert Meade Raucher Wysocki (2)

c) Updates without changes: none

3. Registration documents were reviewed for the following investigators; action taken is indicated.

InvestigatorLevelActionHallBSL-1Tabled pending additional information*.ZhuBSL-2Tabled pending receipt of detailed lentivirus

protocol; major revision of forms

anticipated.

^{*}Additional information requested by Arceneaux, Case, Hardy and Hicock was received by email; based on satisfactory response, approval was granted on 11/15/2004.

Minutes of the Meeting December 10, 2004

Members present:

Dr. J. Lincoln Arceneaux
Mr. Joey Kellum
Mr. William E. Coates
Dr. Gary Reeves
Dr. Andrew W. Grady
Dr. Donna C. Sullivan
Dr. Cheryl S. Hardy
Dr. Jean Walker

Mr. Paul I. Hicock

Members absent:

Dr. Steven T. Case Dr. Rebecca J. R. Waterer Dr. Sarah Lea McGuire Dr. Susan E. Wellman

1. Dr. Andrew Grady chaired the meeting.

2. The minutes of the October 29, 2004 electronic meeting were approved.

3. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

a) b) Updates without changes: Regunathan

McDaniel, L. Lobb

Hosler Drummond

May

McDaniel, O.

waste" on Standardized Plans.

Miller

c) Updates without changes: none

4. Registration documents were reviewed for the following investigators; action taken is indicated.

<u>Investigator</u>	<u>Level</u>	<u>Action</u>
Zhu	BSL-2	Approved pending:
		a) Add statement on health surveillance program to Registration Form.
		 b) Expand Statement of Informed Consent to include HPV symptoms.
Chong	BSL-2	Approved pending:
		a) Check "solid and liquid medical infectious

- b) Submit a completed Occupational Health and Safety Program for Animal Handlers Form.
- c) Check CDC or NIH guidelines on item #5 of Statement of Informed Consent
- 5. Mr. Coates reported that annual unannounced inspections of all BSL-2 and BSL-3 facilities were complete; an itemized list of labs and inspection dates is attached. Most labs were found to be compliant; some had minor deficiencies that were corrected on the spot. Room N-543, the BSL-3 facility, had several items that require follow up: a) there has been at least one incident of a pressure reversal between rooms and b) seals appear to be failing on two ceiling access panels, one of which may contain mold. A maintenance request is being submitted to Physical Facilities by Dr. Jean Arceneaux.
- 6. Mr. Coates reported on the BSL-2 certification inspection conducted on July 8, 2004 in conjunction with Dr. Wein's human gene therapy protocol (detailed report attached). Rooms inspected include H-032-2 (pharmacy), H-324 (patient room on 3 west), OR 1 and OR 2 (surgery), SICU 18 (surgical intensive care unit patient room) and X-509 (stem cell lab). All rooms were compliant and, based on Mr. Coates' recommendation; BSL-2 certification of these rooms for Dr. Wein's protocol was approved.
- 7. Information was distributed regarding "The Sunshine Project" and a memorandum from the NIH Office of Biotechnology Activities about review of recombinant DNA studies.
- 8. The meeting adjourned at 1:35 pm

Minutes of the Electronic Meeting January 28, 2005

Members participating:

Dr. J. Lincoln Arceneaux Dr. Sarah Lea McGuire

Dr. Steven T. Case Dr. Gary Reeves

Mr. William E. Coates Dr. Donna C. Sullivan

Dr. Andrew W. Grady Dr. Jean Walker

Dr. Cheryl S. Hardy
Dr. Rebecca J. R. Waterer
Mr. Paul I. Hicock
Dr. Susan E. Wellman

Mr. Joey Kellum

1. Minutes of the December 10, 2004 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes: May

McDaniel, L. Sinning (2) Woolverton Kermode Lobert

c) Updates without changes: Lundrigan

3. Registration documents were reviewed for the following investigators; action taken is indicated.

<u>Investigator</u> <u>Level</u> <u>Action</u>

Farley BSL-2 Based on subsequent exchange of email,

approval was granted without the need to list

specific bloodborne pathogens.

Minutes of the Electronic Meeting February 25, 2005

Members participating:

Dr. J. Lincoln Arceneaux
Dr. Sarah Lea McGuire
Dr. Steven T. Case
Dr. Donna C. Sullivan
Mr. William E. Coates
Dr. Jean Walker

Dr. Andrew W. Grady
Mr. Paul I. Hicock
Dr. Rebecca J. R. Waterer
Dr. Susan E. Wellman

Members not participating:

Dr. Cheryl S. Hardy Dr. Gary Reeves

Mr. Joey Kellum

- 1. Minutes of the January 28, 2005 Electronic Meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes: Regunathan

Woolverton Chinchar

c) Updates without changes: Chinchar

Olson Gu Choi

3. Registration documents were reviewed for the following investigators; action taken is indicated. .

<u>investigator</u>	Level	Action
Drummond	BSL-2	Pending correction of citation
Adair	BSL-2	Pending correction of citation

- 4. Mr. Coates reported BSL-2 certification inspections on Dr. Chong and Dr. Farley and both were approved.
- 5. The meeting adjourned at 1:50.

Minutes of the Electronic Meeting March 25, 2005

Members participating:

Dr. J. Lincoln Arceneaux Dr. Sarah Lea McGuire

Dr. Steven T. Case Dr. Gary Reeves

Mr. William E. Coates Dr. Donna C. Sullivan

Dr. Andrew W. Grady Dr. Jean Walker

Dr. Cheryl S. Hardy Dr. Susan E. Wellman

Mr. Paul I. Hicock

Members not participating:

Mr. Joey Kellum Dr. Rebecca J. R. Waterer

1. Minutes of the February 25, 2005 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

a) b) Updates without changes: Raucher

McDaniel L.

Duhe Hebert (2)

c) Updates without changes: none

Minutes of the Meeting April 29, 2005 1:00 PM

Members present:

Dr. J. Lincoln Arceneaux
Dr. Sarah Lea McGuire
Dr. Steven T. Case
Dr. Gary Reeves
Mr. William E. Coates
Dr. Donna C. Sullivan
Dr. Andrew W. Grady
Dr. Rebecca J. R. Waterer
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman

Members absent:

Mr. Joey Kellum Dr. Jean Walker

- 1. The minutes of the June 24, 2005 electronic meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

a) b) Updates without changes: Raucher

Zhou Zhu (2) Regunathan

Liu Duhe (2) Hebert Liu

c) Updates without changes: Zhu

3. Registration documents were reviewed for the following investigators; action taken is indicated.

<u>Investigator</u>	<u>Level</u>	<u>Action</u>
Gu	BSL-2	
Granger	BSL-2	
Smith	BSL-2	
Iyo	BSL-2	

4. Mr. Coates reported on the BSL-2 certification inspection for the following people:

Zhou Wysocki Wein Taybos Flow Ctometry

All rooms were compliant and, based on Mr. Coates' recommendation; BSL-2 certification of these rooms was approved.

5. The meeting adjourned at 1:44 pm.

Minutes of the Electronic Meeting May 27, 2005

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Dr. J. Lincoln Arceneaux Mr. Joey Kellum
Dr. Steven T. Case Dr. Gary Reeves
Dr. Andrew W. Grady Dr. Jean Walker

Mr. Paul I. Hicock Dr. Susan E. Wellman

Members not participating:

Mr. William E. Coates Dr. Donna C. Sullivan Dr. Cheryl S. Hardy Dr. Rebecca J. R. Waterer

Dr. Sarah Lea McGuire

1. Minutes of the April 29, 2005 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

a) b) Updates without changes: Stec

Lobert

c) Updates without changes: none

Minutes of the Electronic Meeting June 24, 2005

Members participating:

Dr. J. Lincoln Arceneaux
Dr. Steven T. Case
Mr. William E. Coates
Dr. Donna C. Sullivan
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman
Mr. Paul I. Hicock
Dr. Rebecca J. R. Waterer

Members not participating:

Dr. Andrew W. Grady
Dr. Jean Walker
Dr. Sarah Lea McGuire

- 1. Minutes of the May 27, 2005 Electronic Meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes: Zhu

Lobert
Meade
Liu
Choi
McDaniel
Hosler
Hebert

Woolverton (2)

c) Updates with changes: none

3. Mr. William Coates BSL-2 certification inspection of Dr. O'Callaghan's facilities was approved.

Minutes of the Meeting July 29, 2005 at 1:00 PM Room R-136

Members present:

Dr. J. Lincoln Arceneaux
Dr. Steven T. Case
Dr. Donna C. Sullivan
Mr. William E. Coates
Dr. Rebecca J. R. Waterer
Dr. Andrew W. Grady
Dr. Sarah Lea McGuire

Members absent:

Dr. Cheryl S. Hardy Mr. Joey Kellum Dr. Jean Walker

- 1. The minutes of the June 24, 2005 electronic meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

a) b) Updates without changes: Raucher

Zhou Zhu (2) Regunathan

Liu Duhe (2) Hebert Liu

c) Updates without changes: Zhu

3. Registration documents were reviewed for the following investigators; action taken is indicated.

<u>Investigator</u>	<u>Level</u>	<u>Action</u>
Gu	BSL-2	Approval pending modifications to registration form
Granger	BSL-2	Approval pending modifications to registration form
Smith	BSL-2	Approval pending modifications to registration form
Iyo	BSL-2	Approval pending modifications to registration form

4. Mr. Coates reported on unannounced BSL-2 annual inspections for the following people:

Zhou Wysocki Wein Taybos Flow Cytometry

All rooms were compliant and, based on Mr. Coates' recommendation; BSL-2 re-certification of these rooms was approved.

- 5. Dr. Case noted that to date, about 50% of registered supervisors have submitted Annual Renewal forms.
- 6. The meeting adjourned at 1:44 pm.

Minutes of the Electronic Meeting August 26, 2005

Members participating:

Dr. J. Lincoln Arceneaux
Dr. Gary Reeves
Dr. Steven T. Case
Dr. Donna C. Sullivan
Dr. Rebecca J. R. Waterer
Dr. Andrew W. Grady
Dr. Susan E. Wellman
Dr. Cheryl S. Hardy
Dr. Jean Walker
Mr. Joey Kellum

Members not participating:

Dr. Sarah Lea McGuire

- 1. The minutes of the July 29, 2005 meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes Olson

Raucher

c) Updates with changes: Farley

Chong

Minutes of the Electronic Meeting September 30, 2005

Members participating:

Dr. Steven T. Case
Dr. Andrew W. Grady

Dr. Cheryl S. Hardy

Mr. Joev Kellum

Dr. Sarah Lea McGuire

Dr. Gary Reeves

Dr. Donna C. Sullivan

Dr. Rebecca J. R. Waterer Dr. Susan E. Wellman

Dr. Jean Walker

Members not participating:

Dr. J. Lincoln Arceneaux

Dr. Hamed Benghuzzi

Mr. William E. Coates

- 1. The minutes of the August 26, 2005 electronic meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects:

none

b) Updates without changes

Farley Wellman Woolverton

Hall

O'Callaghan

c) Updates with changes:

Sullivan (room change, add personnel)

Microbiology 610/710 (add new pathogens) Chong (add human cell lines and personnel)

3. Registration documents were reviewed for the following investigators; action taken is indicated.

<u>Investigator</u> Flowers <u>Level</u> BSL-2

Action Approved

Minutes of the Electronic Meeting October 28, 2005

Members participating:

Dr. Steven T. Case
Dr. J. Lincoln Arceneaux
Dr. Donna C. Sullivan
Dr. Cheryl S. Hardy
Dr. Rebecca J. R. Waterer
Mr. Joey Kellum
Dr. Sarah Lea McGuire

Members not participating:

Dr. Hamed Benghuzzi
Mr. William E. Coates
Dr. Andrew W. Grady
Dr. Jean Walker

- 1. The minutes of the September 30, 2005 electronic meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes Liu

Meade (2) Duhe Wysocki

c) Updates with changes: Lobert (Additional E.coli K12 vector)

Minutes of the Meeting December 9, 2005 1:00 PM

Members participating:

Dr. J. Lincoln Arceneaux
Dr. Gary Reeves
Dr. Hamed Benghuzzi
Dr. Jean Walker
Mr. William E. Coates
Dr. Susan E. Wellman

Dr. Andrew W. Grady

Members not participating:

Dr. Steven T. Case
Dr. Sarah Lea McGuire
Dr. Cheryl S. Hardy
Dr. Donna C. Sullivan
Dr. Rebecca J. R. Waterer

- 1. Dr. Andrew Grady chaired the meeting.
- 2. The minutes of the October 28, 2005 electronic meeting were approved.
- 3. The following Registrations and Updates granted Chair approval were accepted.

a) Exempt projects: none

b) Updates without changes Hosler Gu

Raucher

c) Updates with changes: none

4. Registration documents were reviewed for the following investigators; the action taken is indicated.

Investigator Level Action

Reckelhoff BSL-2 Approved pending correction on registration form

5. Mr. Coates reported on BSL-2 certification inspections for the following:

Investigator Action
Granger Approved
Gu Approved
Flowers Approved
Smith Approved

6. Mr. Coates reported on unannounced annual biosafety inspections of laboratories supervised by the following investigators. Other than minor on-the spot- corrections, all were found to be compliant:

Byers

Duhe

Hines

Lundrigan

Jenkins

Kramer

Norcum

Olson

Regunathan

Sulllivan

Woolverton

7. Mr. Coates reported the Centers for Disease Control and Prevention (CDC) inspection of UMC's BSL-3 suite (N543, N543-1, N-543-2) that took place on October 7, 2005 and audit of records with regard to renewal of this entity's registration for the select agent program. The major emphasis was on security (of select agents and records) and biosafety. A detailed response to all comments including revised security, biosafety, and emergency plans were submitted on December 2nd. CDC approval was granted on December 7 for a period extending up to May 4, 2008.

8. The meeting was adjourned at 1:28 PM.

Minutes of the Meeting January 27, 2006 Room 136 1:00 PM

Members participating:

Dr. J. Lincoln Arceneaux Dr. Hamed Benghuzzi Dr. Steven T. Case Dr. Andrew W. Grady Dr. Cheryl S. Hardy Mr. Joey Kellum Dr. Gary Reeves
Dr. Donna C. Sullivan
Dr. Jean Walker
Dr. Susan E. Wellman
Dr. Rebecca J. R. Waterer

Members not participating:

Dr. Sarah Lea McGuire

- 1. The minutes of the December 9, 2005 meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted; however, a change in year ("2005" to "2006") was needed for entries for Iyo through Kermode in the IBC database.

a) Exempt projects:

none

b) Updates without changes

Chinchar Hebert May Iyo Gu Liu Kermode

c) Updates with changes:

none

3. Registration documents were reviewed for the following investigators; the action taken is indicated.

<u>Investigator</u> <u>Level</u> <u>Action</u>
Vick BSL-2 Approved pending status as faculty

- 4. An announcement was made that IBC members will conduct BSL-2 certification inspections until a new Biosafety Officer is appointed. BSL-2 and BSL-3 inspections forms were reviewed. Mr. Joey Kellum has agreed to do the first inspection assisted by Dr. Jean Walker.
- 5. Dr. Arceneuax observed someone transporting what appeared to be a potential biohazard through the School of Medicine lobby. Dr. Case encouraged everyone to make on-the-spot inquires when such events are observed. Meanwhile, he will send an email to all faculty

reminding them that biohazards must be contained in appropriate containers when transported outside of their lab and that public areas should be avoided, when possible.

6. The meeting was adjourned at 1:45 PM.

Minutes of the Electronic Meeting February 24, 2006

Members participating:

Dr. Steven T. Case
Dr. Donna C. Sullivan
Dr. J. Lincoln Arceneaux
Dr. Rebecca J. R. Waterer
Dr. Andrew W. Grady
Dr. Susan E. Wellman
Mr. Joey Kellum
Dr. Jean Walker

Dr. Gary Reeves

Members not participating:

Dr. Hamed Benghuzzi Dr. Sarah Lea McGuire

Dr. Cheryl S. Hardy

1. The minutes of the January 27, 2006 meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) New projects: none

b) Updates without changes Farley

Wellman Raucher (2) Zhou

Hebert (2)

Gu Iyo

c) Updates with changes: none

3. Mr. Kellum's certification inspection report for Dr. Reckelhoff's lab at BSL-2 was approved pending changes noted in the attached report..

Minutes of the Electronic Meeting March 31, 2006

Members participating:

Dr. Steven T. Case

Dr. Donna C. Sullivan

Dr. J. Lincoln Arceneaux

Dr. Rebecca J. R. Waterer

Dr. Hamed Benghuzzi

Dr. Susan E. Wellman

Dr. Cheryl S. Hardy

Dr. Jean Walker

Dr. Gary Reeves

Members not participating:

Dr. Andrew W. Grady

Dr. Sarah Lea McGuire

Mr. Joey Kellum

1. The minutes of the February 24, 2006 electronic meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) New projects:

none

b) Updates without changes

Woodley

Gu

Zhu

Raucher

c) Updates with changes:

Chinchar

Meade

Minutes of the Meeting April 28, 2006 1:00 PM

Members participating:

Dr. Steven T. Case Dr. Jean Walker

Dr. Andrew W. Grady
Dr. Rebecca J. R. Waterer
Dr. Gary Reeves
Dr. Susan E. Wellman

Dr. Donna C. Sullivan

Members not participating:

Dr. J. Lincoln Arceneaux Mr. Joey Kellum

Dr. Hamed Benghuzzi Dr. Sarah Lea McGuire

Dr. Cheryl S. Hardy

1. The minutes of the March 31, 2006 electronic meeting were approved.

- 2. No Registrations and Updates were granted Chair approval this month, were accepted.
- 3. Registration documents were reviewed for the following investigators; the action taken is indicated.

Investigator Level Action

Flessner BSL-2 Approved pending correction on registration form

4. Registration documents submitted late were reviewed for the following investigators; the action taken is indicated. These were added to the agenda.

InvestigatorLevelActionClearyBSL-2Approved pending corrections on Registration formLamBSL-2Approved.

- 5. It was bought to the IBC's attention that a select agent, for which UMC is not registered to possess, was found in the Hazardous Materials Storage Room G040 on April 20, 2006 by Mr. Thomas O. Saffle, and Dr. Arthur Hume. Dr. Case was informed on April 24, 2006, the incident was reported to the Centers for Disease Control and Prevention (CDC) Select Agent Program, the material was detoxified in the BSL-3 facility and properly disposed of and a detailed report provided to the CDC.
- 6. The meeting was adjourned at 1:35 PM.

Minutes of the Electronic Meeting May 26, 2006

Members participating:

Dr. Hamed Benghuzzi Dr. Gary Reeves Dr. Steven T. Case Dr. Jean Walker

Dr. Andrew W. Grady
Dr. Rebecca J. R. Waterer
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman

Mr. Joey Kellum

Members not participating:

Dr. J. Lincoln Arceneaux Dr. Donna C. Sullivan

Dr. Sarah Lea McGuire

1. The minutes of the April 28, 2006 electronic meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) New projects: none

b) Updates without changes Davidson

Iyo Cleary

c) Updates with changes: Brown

Kramer Raucher

3. Registration documents were reviewed for the following investigators; the action taken is indicated.

<u>Investigator</u> <u>Level</u> <u>Action</u> daSilva BSL-2 Approved

Minutes of the Electronic Meeting June 30, 2006

Members participating:

Dr. J. Lincoln Arceneaux Dr. Gary Reeves Dr. Steven T. Case Dr. Jean Walker

Dr. Andrew W. Grady
Dr. Rebecca J. R. Waterer
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman

Mr. Joey Kellum

Members not participating:

Dr. Hamed Benghuzzi Dr. Donna C. Sullivan

Dr. Sarah Lea McGuire

1. The minutes of the May 26, 2006 electronic meeting were approved.

2. The following Registrations and Updates granted Chair approval were accepted.

a) New projects: Pang

b) Updates without changes Gu

Granger
Hebert
Lobert (2)
O'Callaghan
Regunathan

Zhou Zhu

c) Updates with changes: none

3. Report on certification inspection for the following investigator was approved.

<u>Investigator</u> <u>Level</u> Lam <u>BSL-2</u>

Minutes of the Electronic Meeting July 28, 2006

Members participating:

Dr. J. Lincoln Arceneaux

Dr. Steven T. Case

Dr. Cheryl S. Hardy

Dr. Donna C. Sullivan

Dr. Jean Walker

Dr. Rebecca J. R. Waterer

Dr. Gary Reeves

Dr. Susan E. Wellman

Members not participating:

Dr. Hamed Benghuzzi

Dr. Andrew W. Grady

Mr. Joey Kellum

Dr. Sarah Lea McGuire

- 1. The minutes of the June 30, 2006 electronic meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) New projects:

none

b) Updates without changes

Liu Gu

> O'Callaghan Reckelhoff Woolverton

Zhou

c) Updates with changes:

Lobert (2)

3. Report on certification inspection for the following investigator was approved.

<u>Investigator</u>

Level

Lam

BSL-2

Minutes of the Electronic Meeting August 25, 2006

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Dr. J. Lincoln Arceneaux
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Dr. Steven T. Case
Dr. Jean Walker

Dr. Andrew W. Grady
Dr. Rebecca J. R. Waterer
Dr. Cheryl S. Hardy
Dr. Susan E. Wellman

Mr. Joey Kellum

Members not participating:

Dr. Sarah Lea McGuire

c) Updates with changes:

- 1. The minutes of the July 28, 2006 electronic meeting were approved.
- 2. The following Registrations and Updates granted Chair approval were accepted.

a) New projects: none

b) Updates without changes Hebert (2)

Iyo Kermode Liu Raucher Woolverton

3. Report on certification inspection for the following investigator was approved.

<u>Investigator</u> <u>Level</u> Cleary BSL-2

4. Reports from IBC members who conducted unannounced annual BSL-2 inspections will be done at the meeting on September 29, 2006.

Duhe