DENVER & HEALTH SCIENCES CENTER

Office of the Vice Chancellor for Research, Dept. of Environmental Health and Safety
Attn.: Biosafety Officer, MS F484
P. O Box 6508
Aurora, CO 80045
(303) 724-0245

April 28, 2006

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

Dear Mr. Hammond:

I am responding to your request for the minutes of all meetings of the University of Colorado at Denver and Health Sciences Center ("UCDHSC") Institutional Biosafety Committee since May 1, 2003. Your request was made pursuant to NIH Guidelines, Section IV-B-2-a-(7) and the not the Colorado Open Records Act.

In response to your request please find the IBC meeting minutes dated April 8, 2005, August 5, 2005, September 30, 2005, October 28, 2005, December 5, 2005, January 27, 2006, and February 24, 2006 attached. The UCDHSC IBC did not meet formally prior to April 8, 2005, and therefore, does not have meeting minutes prior to this date.

Information referencing individual reviewers and references to items of business conducted by the IBC that do not relate to its role and responsibilities under NIH Guidelines has been redacted. In addition, confidential information concerning the details of research protocols has been redacted.

In response to your question regarding the identification, review, and oversight of research involving the seven categories of experiments of concern, our IBC authorization form requires the investigator to disclose whether any of the following categories apply to his/her project:

1. Renders a useful vaccine ineffective
2. Adds antibiotic resistance affecting response to a clinically useful drug
3. Enhances pathogen virulence
4. Increases pathogen transmissibility
5. Widens a pathogen's host range
6. Lets a pathogen evade diagnostic or detection modalities
7. Weaponization (e.g. environmental stabilization or pathogens)

Sincerely,

Therese Stinnett
Biosafety Officer, UCDHSC Health and Safety Division

Minutes

Institutional Biosafety Committee
CFAR Conference Room
School of Medicine, Room 2801
April 8, 2005 – 3 p.m.

I. Call to Order
Attendees:
Dr. Campbell, Chair,
Therese Stinnett
Terry Howard
Larry Sater

II. Committee Membership--Discussion

A. Introduction & Appointment of new Community Members
1. Larry Sater, Colorado Dept. of Public Health & Environment
2. Todd Bergren, PhD, Professor, Biology, Community College of Aurora

B. Appointment of Institutional Veterinarian
James Stevens, DVM, UCDHSC

C. NIH Requirements for Committee Membership

1. Appointment of Technical Staff representative—currently vacant

**"Section IV-B-2-a-(2).** ...and (iii) include at least one member representing the laboratory technical staff"

The Biosafety Officer was directed to try to recruit a suitable technical staff member (PRA) from the research community.

2. Recruitment of additional faculty

Discussion ensued on the difficulty of managing protocol reviews, especially for HGT protocols with low numbers for faculty participation in the committee. Mr. Howard and Ms. Stinnett have discussed this with the VC for Research and are actively seeking to recruit new faculty to this committee. Names will be forwarded to Dr. Sladek as faculty express an interest.

D. Regent Policy on Indemnification (attachment 1) and Colorado Governmental Immunity Act

Information is provided to the committee members, to include the community members on the policies and regulations regarding indemnification for IBC members.

Per the UCDHSC IBC by-laws: "The chair and membership of the IBC acts as an agent of the institution (UCHSC) and is indemnified per CU Board of Regents policy, in the event of any claim asserted against the IBC."

III. NIH Compliance Reminders & Site Visit announcement (Attachment 2)

A. Committee Meetings
1. Meeting Schedule

Ms. Stinnett presented information regarding proposed meeting schedule for the upcoming academic-fiscal year. Unless committee business dictates otherwise, a quarterly meeting is the preferred schedule at this time.

2. Recording Minutes (attachment 3)

Ms. Stinnett presented information from a recent ARENA/PRIMR conference she attended on IBC meeting requirements. Mr Alan Shipp and others from NIH-OBA put on a day long seminar on the meeting and minutes-keeping requirements.

3. How and when to make meetings and minutes public?

"**Section IV-B-2-a-(6).** When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its Institutional Biosafety Committee meetings to the public."

Discussion ensued. The *NIH Guidelines* do not prescribe how IBCs should be convened, but they do speak to the preparation of meeting minutes (Section IV-B-2-a-(7)), and they encourage institutions to accommodate public attendance at meetings (Section IV-B-2-a-(6)).

Thus, IBCs should be convened in a manner that allows for fulfillment of these two expectations. In general, email exchanges cannot fulfill these expectations of the *NIH Guidelines*, and thus it is not acceptable for IBCs to "meet" by email.

B. Committee Documents & Records-Management

1. Federal—Freedom of Information Act
2. State of Colorado—Open Records Act
3. How and when to make public?

**"Section IV-B-2-a-(7).** Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Biotechnology Activities, NIH..."

Discussion ensued on how to present this information. EHS, Biosafety Office will

prepare an IBC webpage for the UCHSC web.

IV. Collaboration/Research Agreement with The Children's Hospital

Draft agreement language (Attachment 4) was discussed. TCH will be establishing their own IBC for managing their own rDNA and HGT research.

V. Protocol Reviews

A. Review of New Proposals

No new protocols for review. Discussion ensued on managing protocol submissions, particularly HGT protocols in a timely manner.

B. Annual Review Requirements

Discussion on how best to manage annual reviews of protocols that require such reviews.

VI. Biosafety Training

Information on the proposed Curriculum & Documentation for training was presented by the Biosafety Officer.

VII. Scheduling of next meeting

Tentatively scheduled for the fourth Friday in August. Time and location to be announced.

VIII. Adjournment

# Minutes

## Institutional Biosafety Committee
Friday, August 5, 2005
9 a.m., Teleconference

I. Call to Order

The meeting was called to order at 9:05 a.m.

The following individuals were in attendance by teleconference:
Dr. Thomas B. Campbell, MD, Chair
Therese M. Stinnett, Biosafety Officer/IBC Administrator
Mr. Larry Sater, Community Member
Dr. James Stevens, DVM
Dr. Jerry Schaack, PhD, Reviewer
Dr. Lynne Bemis, PhD, Reviewer

II. Old Business

A. Minutes of April 2005 Meeting
The minutes had been distributed by email to all committee members. There were no corrections or additions noted. Motion to approve and seconded. Motion passed by acclamation.

B. Committee Membership & Appointments

1. Appointment of New Committee Members
Dr. Kathryn V. Holmes, Microbiology
Dr. Madeleine Kane, Medical Oncology
2. Appointment of Ad Hoc/Consulting Member
Dr. Lynne Bemis, Medical Oncology

III. New Business

A. Protocol Reviews

1. "A Phase I, Multi-Center, Open-Label, Dose-Escalation Trial to Evaluate the Safety of Intratumoral VCL-IM01 Followed by Electroporation", Vical, Inc.

Reviewers: [redacted]

[redacted] provided a summary of the HGT protocol. [redacted]

Motion to approve, seconded and carried. (6 approved; no abstentions)

2. Nomination of additional committee member.

Ms. Stinnett informed the committee that the Select Agents regulation requires at least the appointment of a "Responsible Official" for the campus and allows for the appointment of an "Alternate RO" so that some one is always available.

With the retirement of the Director of Health and Safety, Ms. Stinnett has been named the campus RO in his place, by Dr. Sladek, Vice Chancellor for Research.

She nominated Mr. Louis Mitchell, the HSD Senior Industrial Hygienist, as the ARO and Dr. Sladek has accepted that and appointed him. Ms. Stinnett suggested he be added to the IBC to assist with the review of any SA protocols.

Motion to approve the nomination of Mr. Mitchell to the IBC, seconded and carried. (6 approved; no abstentions)

B. NIH Office of Biotechnology Activities & Compliance

1. Annual Report to NIH/OBA

Ms. Stinnett reminded the IBC that the annual report to NIH/OBA would be due in September, 2005. This consists of the current roster of committee members, with CVs for all new members.

Action Item: This report will be submitted by the Biosafety Office.

2. NIH OBA Presentations from "IBC Basics" March 12, 2005
http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm

Ms. Stinnett discussed her attendance at the IBC Basics seminar in March, as well as the initiatives underway with the Office of Biotechnology Activities & Compliance with regard to IBC structures, functions and NIH expectations.

3. IBC Webpage Development
http://www.uchsc.edu/safety/BioSafety/InstBioSafCommittee.htm

Ms. Stinnett reported that the Biosafety Office, with the Health and Safety Division has created a web page for the IBC. It is going to see additional development as time and resources permit.

C. Other Committee Business

1. Meeting Schedule & Protocol Submission Deadlines & Meeting with Cancer Center Representatives

Dr. Campbell (by teleconference) and Ms. Stinnett met with representatives of the University of Colorado Cancer Center on July 27th, 2005 to discuss improving communication between the researchers of the Clinical Investigation Core and the Biosafety Office on behalf of the IBC as well as the timeliness of review processes.

The UCCC representatives were: Dr. Madeline Kane, MD; Ms. Erin Conlin, Regulatory Affairs Manager, and Ms. Andrea Buchmeier of the CIC.

It was proposed that a monthly meeting schedule, along with deadlines for submissions, be developed and published (using the new website and other campus communications). Ms. Stinnett will prepare this for distribution to the committee and campus.

The current Biosafety authorization form (UCHSC Form 86-1) presents difficulties when used for Human gene transfer (HGT) clinical trials. It was agreed that this form could and should be dropped for these specific experiments and that a standardized cover letter for HGT would be more useful along with the responses to Appendix M questions as specified by NIH.

It was explained that the Appendix M requirements of the NIH Guidelines require UCDHSC-specific answers to each question, so that the sponsor's answers to Appendix M are not sufficient for the local review process. Ms. Conlin will work with PIs to assure the Appendix M is completed correctly.

Upon submission, each HGT protocol will go to two (2) primary reviewers. The IBC will request the primary reviewers provide a written summary of each HGT protocol and any requests for additional details or information, to the Biosafety Office, within 2 weeks of receiving the protocols. This will provide the CIC with a framework and timeline for responding. All information (summary, reviewer comments, etc) will be distributed to the IBC at least one week prior to the scheduled IBC meeting for their consideration.

In addition, Dr. Kane invited Ms. Stinnett, and Dr. Campbell, to attend the Cancer Center Clinical Study PI meeting in October, to provide a short presentation on the NIH Guidelines and the role and responsibilities of the IBC as they pertain to HGT clinical trials.

Action Item: Biosafety Office will develop 2005-2006 calendar of meetings and submission deadlines.

Action Item: Development of standard cover letter/cover sheet for the submission of HGT clinical trials.

Action Item: Brief presentation to the Clinical Study PIs tentatively scheduled for October.

2. Annual Report to SOM Faculty Senate

The SOM Faculty Senate has requested an annual report from the IBC. It will be prepared by the Biosafety Office and reviewed by Dr. Campbell for submission.

Action Item: Submission of an annual report by August 31st deadline.

D. Biosafety Program Issues

[redacted]

3. Training Programs

Ms. Stinnett gave a brief run-down of the current training being offered through the Health and Safety Division, on-line in the Blackboard system.

E. IBC Continuing Education

1. First Meeting of the National Science Advisory Board for Biosecurity, archived meeting webcast http://www.biosecurityboard.gov/meetings.asp

2. National Academies Press publication of National Research Council & Institute of Medicine Guidelines for Human Embryonic Stem Cell Research http://www.nap.edu/books/0309096537/html/

F. Other Business

None

IV. Adjournment

There being no other business, there was a motion to adjourn, seconded and carried. The meeting adjourned at 9:40 a.m.

# Minutes

## Institutional Biosafety Committee
## Friday, September 30, 2005

## SOM 2801, CFAR Conference Room

I. Call to Order

Meeting was called to order at 12 noon.
The following individuals were in attendance:

Dr. Thomas B. Campbell, MD, Chair
Dr. Katherine Holmes (late arrival)
Therese M. Stinnett, Biosafety Officer/IBC Administrator
Mr. Louis Mitchell, CIH, Health and Safety Division
Mr. Larry Sater, Community Member
Dr. James Stevens, DVM

II. Old Business

A. Minutes of August 2005 Meeting

Minutes were distributed by email. Motion to approve, seconded. Minutes were approved (5-0)

B. Meeting Schedule/Protocol Submission Deadlines (proposed calendar)

Discussion on the proposed calendar. Thursdays, after 3 p.m. may be an acceptable alternative to Fridays, for the committee meetings. The committee will be polled by email by the Biosafety Office on that alternative.

C. Annual Report to SOM Faculty Senate (attachment)

The report was submitted to meet the September 30th deadline.

D. IBC Webpage Development

The Biosafety Officer briefly discussed the intent for the new IBC webpage. The committee calendar and deadlines for submission of protocols will be published as soon as finalized.

III. New Business

A. Protocol Reviews

1. "A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter, Dose-Selection Study of Ad2/Hypoxia Inducible Factor (HIF)-1α/VP16 in Patients with Intermittent Claudication" PI: Mark Nehler, MD, Vascular Surgery

Designated Reviewers--[redacted]

[redacted] provided the following summary of the protocol (in email correspondence) and recommended approval.

[redacted]

Motion to approve, seconded and approved (6-0)

2. Dept. of Microbiology [redacted].

There was a brief discussion regarding the infectious materials, the training and the status of the new laboratories. There was a motion to approve the research projects submitted by Dept. of Microbiology investigators; seconded and approved (6-0).

3. HGT Protocol—Closed to Accrual

"A Multicenter, Double-blind, Placebo-Controlled, Phase II Study of Aerosolized TGAVVCF for the Treatment of Cystic Fibrosis" PI: Frank Accurso, MD, Sponsor: Targeted Genetics, Inc.

All enrolled subjects will be participating in long-term follow-up by COMIRB.

B. NIH Office of Biotechnology Activities

1. Annual Report to NIH/OBA (attached)
The annual report to NIH/OBA was submitted by the Biosafety Office to meet the September deadline

2. News from OBA—nothing to report

C. Biosafety Program Issues

[redacted]

3. Training Programs

The Biosafety Officer and Mr. Mitchell brought the committee up-to-date on the status of the training program for BSL3 users and for the research community in general. Bloodborne Pathogens/Exposure Control training is on-line but is not sufficient alone for the broad category of biosafety training. University Leadership Development Initiative (ULDI) which has provided some financial support in the past, will continue to fund that and the Shipping training. The latter is undergoing revision. As time and resources permit the intention is to put additional training modules on-line in the Blackboard system.

D. IBC Continuing Education

1. Draft Guidance for Industry on Gene Therapy Clinical Trials--

Observing Participants for Delayed Adverse Events. Written or electronic comments on the draft guidance are due by November **21**, 2005.

E. Other Business

1. Research Compliance

There is a position announcement for the newly created Assistant Vice Chancellor of Regulatory Compliance for Research Affairs. This will upgrade the former Director of Regulatory Compliance position, and it appears it will be a direct report to the Chancellor.

2. Consolidation Study for EHS Director position (attachment).

The Chancellor for UCDHSC and Vice Chancellors for Administration at UCDHSC and CU-Boulder have initiated a study to consider consolidation of the currently vacant Health and Safety Director positions at both campuses. The study was undertaken by the Interim Director at CU-Boulder, Dave Wergin, with input from the Health and Safety Division at UCDHSC, and specifically from the Biosafety Office. There appear to be advantages and disadvantages to this and a report is due to the Chancellor on October

1st. As CU-Boulder has already initiated a national search for their vacancy this is a very timely issue.

IV. Adjournment

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

# Minutes

Institutional Biosafety Committee
Friday, October 28, 2005

Teleconference, 1:30 p.m.

I. Call to Order
Attendees:
- Stinnett
- Holmes
- Mitchell
- Stevens
- Sater
- Bergren

The business items were taken out of order, due to Mr. Mitchell's need to depart at 2 pm. The committee discussed and voted on the New Business (protocol reviews) first.

II. New Business

A. Protocol Reviews

1. IBC # 06-004, "A Phase III Randomized, Open-Label Study of CG1940 and CG8711 Versus Docetaxel and Estramustine in Patients with Metastatic Hormone-Refractory Prostate Cancer who are Chemotherapy-Naive"
PI: M. Glode, MD
Sponsor: Cell Genesys

Designated reviewers—[redacted]

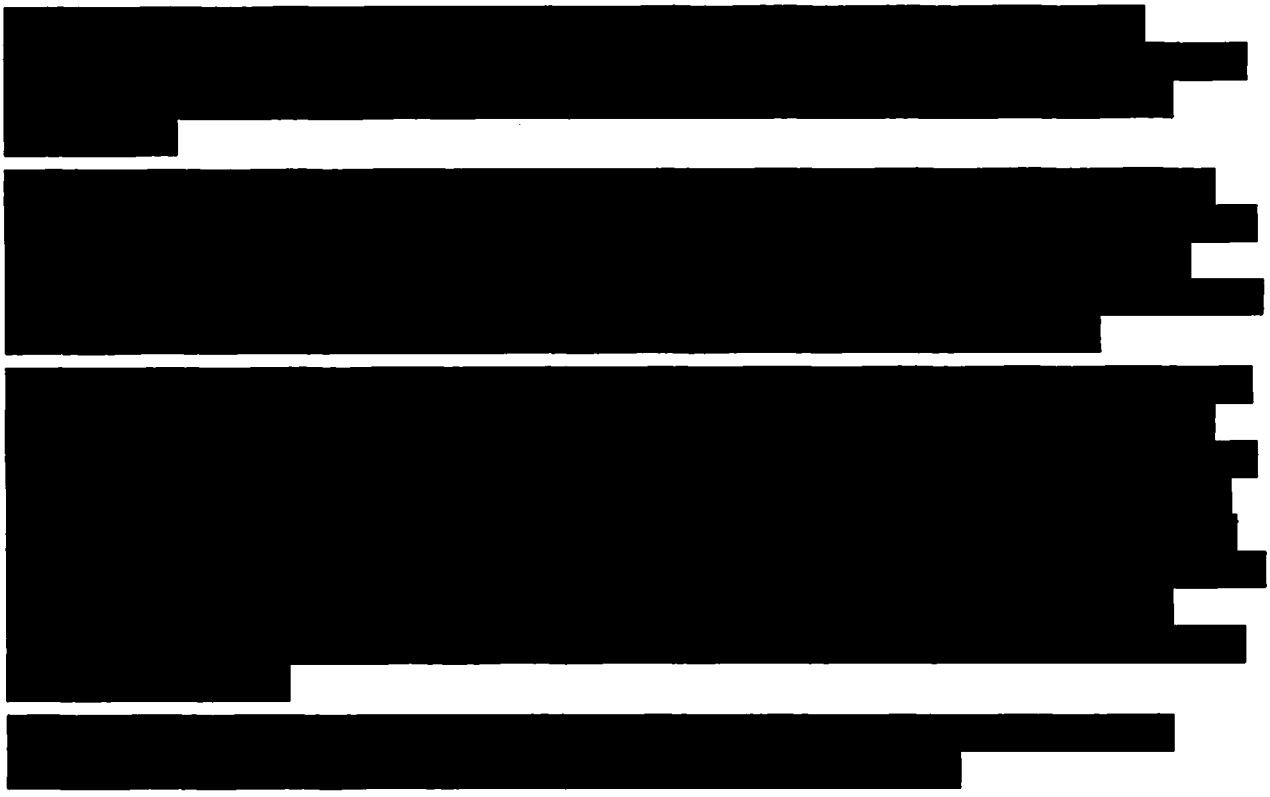
A complete protocol was submitted, including a detailed, UCDHSC-specific Appendix M for this protocol, along with the UCDHSC Biosafety Authorization forms and the Informed Consent, as reviewed by the COMIRB on August 22, 2005.

[redacted]

A motion to approve was made and seconded. The protocol was approved.

2. IBC # 06-005, Yeast-Platform Influenza Vaccine in Murine Model, PI: D. Belgrau, Sponsor: GlobeImmune,

Full Committee Review



A motion to approve was made and seconded. The protocol was approved by the IBC, but work may not begin until the IACUC has reviewed and approved it.

3. The Biosafety Officer raised the concern of expanding use of recombinant vaccinia viruses in research. At this time the University does not have a stated policy regarding the occupational health and exposure issues for researchers handling these materials, who've not previously had a smallpox vaccine. The committee briefly discussed the use of recombinant vaccinia viruses and recommended that the Biosafety Office survey other institutions for information on current policies in this regard.

III. Old Business

A. Minutes of September 2005 Meeting
Reviewed and approved as filed with the committee.

B. Meeting Schedule/Protocol Submission Deadlines (revised calendar)
Next meeting to be scheduled for Nov. 17th, 2005 at 3 p.m.

C. Consolidation Study for EHS Director Position

The administration has decided to move forward with the consolidation of the Directors' positions and some administrative functions, for the Dept. of Environmental Health and Safety, AVC-Administration at CU-Boulder, and the Health and Safety Division, OVCR, UCDHSC. A Memorandum of Understanding (MOU) will be executed by University Counsel. Three finalists are under consideration and an offer to a candidate is expected in the next few weeks.

D. Search for AVC, Regulatory Compliance for Research Affairs

Two finalists are under consideration.

E. Biosafety Program Issues

[redacted]

3. Training Programs

Shipping Training

The Biosafety Office reports that on occasion, labs shipping out materials by FEDEX or other carriers, are subject to inspection by the FAA, if the shipments go by air. All persons involved in shipping biological materials, particularly by air, are subject to a mandatory training requirement and frequently the FAA cites University labs when they cannot document such training. The Health and Safety Division provides an on-line training program for all University constituents.

The IBC recommended the HSD send an HSC-Safety Announce regarding the mandatory training requirement and availability of training on-line to the campus community.

4. New Forms.

The committee recommended the development of a Glossary for the research community for use with the new forms.

E. Other Business

There was no other new business.

IV. Adjournment

A motion was made to adjourn and seconded. The meeting adjourned at 1:55 pm.

Minutes
Institutional Biosafety Committee
Monday, Dec 5, 2005

Teleconference, 2:00 p.m.

I. Call to Order

Dr. Campbell, Chair
Therese Stinnett, Biosafety Officer/RO
Louis Mitchell, Director, EHS
Dr. Kay Holmes, Dept. of Microbiology
Larry Sater, Community Member
Dr. Lynne Bemis, Reviewer

II. Old Business

A. Minutes of October 2005 Meeting
Motion to approve, seconded. Minutes approved.

B. Meeting Schedule/Protocol Submission Deadlines

Revised calendar has been published on the website.
http://www.uchsc.edu/safety/BioSafety/InstBioSafCommittee.htm

C. Consolidation of EHS Departments at CU-Boulder and UCDHSC

Mr. Louis Mitchell, appointed Director, consolidated Dept. of EHS, effective 1 Dec 2005.

D. Biosafety Program Issues

[redacted]

III. New Business

A. Protocol Reviews

1. "A Phase I Open Label, Non-randomized, Dose-escalation, Multi-center, Therapeutic Trial of the Safety, Immunogenicity and Efficacy of GI-4000, an Inactivated Recombinant *Saccharomyces cerevisiae* Immunotherapeutic Expressing Three

Different Mutations of the Ras Oncoprotein, in Patients with Solid Tumors Expressing Mutations in Ras" (COMIRB 05-0324) PI Karen Kelly, M.D.

Designated reviewers—[redacted]

Motion to approve, seconded. The protocol was approved.

B. Other Business

For information purposes—teleconferences are limited to 8 participants and usually need to be scheduled thru the UCH telephone operator(s) one business day in advance.

No new protocols were submitted for the December meeting. A December meeting is not needed and will not be scheduled.

IV. Adjournment

No further business at this time. Motion to adjourn, seconded. Adjourned at 2:15 p.m.

Minutes
Institutional Biosafety Committee
Friday, January 27, 2006
Teleconference, 3:15 p.m.

I. Call to Order
Attendees
Campbell
Holmes
Mitchell
Blair, C
Bemis
Stinnett
Sater

II. Old Business

A. Minutes of December 5th, 2005 Meeting—

No changes. Motion to approve, seconded. Approved as submitted

B. Biosafety Program Issues

[redacted]

III. New Business

A. Protocol Reviews

1. "A Phase 3 Randomized, Open-Label Study of Docetaxel in Combination with CG1940 and CG8711 versus Docetaxel and Prednisone in Taxane-Naïve Patients with Metastatic Hormone-Refractory Prostate Cancer With Pain (COMIRB 05-0776) PI: Michael Glode, MD

Designated reviewers—[redacted]

[redacted]

Motion to approve, seconded. Approved without any dissent.

2. IBC # 06011--A Phase II Study of the Efficacy, Safety and Immunogenicity of OncoVex $^{GM\text{-}CSF}$ in Patients with Stage IIIc and IV Malignant Melanoma (COMIRB #05-0015) PI: Rene Gonzalez, MD

Designated reviewers—Campbell, Holmes

[redacted]

[redacted]

The comments will be forwarded to the PI for the items addressed. IBC will vote to approve upon the PI successfully addressing these additional details. PI responses will be reviewed by the Biosafety Officer and referred to the committee if they are not deemed adequate.

B. Other Business

1. Lou Mitchell, Director, EHS met with Angela Wishon, J.D. the newly appointed Assistant Vice Chancellor for Regulatory Compliance

[redacted]

3. HIV gag vaccine protocols.

Per the Biosafety Officer's conversation with Alan Shipp of NIH-OBA, DNA vaccine protocols such as this are subject to local IBC review under Section III-C and Section III-D of the NIH Guidelines, under the general biosafety responsibilities for IBCs.

Ken Easterday, Research Pharmacist at UCH and an ad hoc member of our IBC has informed the Biosafety Office that COMIRB Panel A may have reviewed and approved some similar protocols without referring them to the IBC. These may or may not involve recombinant DNA materials.

The Biosafety Officer is working with COMIRB to search through their database and protocols for any that might have been missed by the IBC.

Typically the IBC/Biosafety Office has seen problems with the correct completion of the COMIRB routing slip by study PIs and staff, who may not be aware they are using recombinant DNA in a clinical trial.

The Biosafety Office is also discussing re-phrasing the information requested on the COMIRB cover sheet to better help in pre-review and as protocols are assigned to the various panels. Panel D has been organized to review high risk protocols, to include human gene transfer studies.

4. IBC Training Opportunities:

Upcoming OBA Presentations and Workshops

There are a number of upcoming events where OBA will be conducting workshops and training sessions of interest to IBCs and others with responsibility for the conduct and oversight of recombinant DNA research.
These include:

- Public Responsibility in Medicine and Research, Annual IACUC Conference ("IBC Basics" course, including effective IBC-IACUC interactions), Boston Park Plaza Hotel, Boston, Massachusetts, March 26-28, 2006
- Biotechnology Industry Organization (BIO), Annual International Convention, Chicago, Illinois, April 9-12, 2006
- Association of Clinical Research Professionals (ACRP), Global Conference and Exhibition, April 28-May 2, 2006

5. Transition to a consolidated EHS Department

The consolidation of the Dept. of Environmental Health & Safety between the UCDHSC and CU-Boulder campuses continues to move forward. Angela Wishon will be the reporting authority/chain of command for UCDHSC-specific business.

IV. Adjournment

Moved, seconded, 3:56 pm

DRAFT Minutes

Institutional Biosafety Committee
Friday, Feb. 24, 2006
Teleconference, 3:00 p.m.

I. Call to Order
Attendees: Campbell, Stinnett, Schaack, Bemis, Sater, Mitchell

II. Old Business

A. Minutes of January 27, 2006 Meeting
Reviewed, motion to approve, seconded, approved

B. Biosafety Program Issues

[redacted]

[redacted]

[redacted]

3. Biomedical Wastes at Fitzsimons campus

The EHS Dept/Biosafety section has been afforded an FTE to take over the actual pickup of wastes from Fitzsimons locations.
Custodial staff will still handle at 9th & Colorado.

4. NHP Infectious Tissues-exposure incident

The Biosafety Office is still investigating the circumstances of the incident and what led to the situation.

5. HIV-gag vaccine and other HGT protocols—collaboration with COMIRB—tabled discussion for the moment

III. New Business

A. Protocol Reviews

1. "A Randomized Phase II Study of Therapeutic Immunization and Treatment Interrupton Among Subjects Who Began Potent Antiretroviral Therapy within 16 Days of Diagnosis of Acute or Recent HIV Infection." PI: Elizabeth Connick, MD, Infectious Disease (COMIRB # 05-1028)

Designated reviewers—[redacted]

Motion to approve with additional details. So moved, seconded. Approve with additional details to be reviewed by the Biosafety Officer and forwarded to the committee if deemed insufficient.

Abstention 1

2. Biosafety Authorization for Renewal

"Fibroblast Growth Factor signaling and Pituitary tumorigenesis" PI: Andrew P. Bradford, OB-Gyn, NIH grant.

Moved, seconded, approved for renewal

B. Other Business

1. MOU with Denver VAMC for Human Gene Transfer Clinical Trials

The IBC supports the concept and the biosafety office should move forward with this collaboration

IV. Adjournment

Move, seconded.