



17 April 2006

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

Re: The Sunshine Project

Dear Mr. Hammond,

As per your formal request of 13 March 2006, please find enclosed copies of the minutes from the Vical IBC meetings from 1 May 2003. The minutes have been redacted in accordance with Section IV-B-2-a-(6) of the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (*NIH Guidelines*) to date.

Regarding your question in reference to the Fink Committee report, "*Biotechnology Research in an Age of Terrorism*," the listed seven classes of "Experiments of Concern" all involve modification of pathogenic organisms in some manner, and do not apply to Vical's research and development. Vical has implemented written procedures in accordance with the *NIH Guidelines*.

Please know that Vical is committed to providing public access to information in full compliance with applicable regulations and guidelines. If you have any further questions, do not hesitate to contact Vical.

Sincerely,

A handwritten signature in black ink that reads "William Wood".

William Wood  
Vical IBC Chairperson

Enclosure

**COPY**

**Vical IBC Meeting Minutes**  
Meeting held on August 18, 2003

**I. Call to Order and Administrative Issues**

The meeting was called to order by chairman, Anita Green at 1:00 p.m.

Introduction of IBC Members –Anita Green

IBC Chairman: Anita Green (voting member), Safety Manager, Vical  
IBC Administrator: Michelle Yu (non-voting member), Regulatory Affairs Associate,  
Vical

Voting members of IBC in attendance:

Anita Green, Chairperson, Biosafety Officer, Vical  
Catherine Luke, Ph.D., Research Scientist II, Vical  
Brenda Wong, Biosafety Officer, UCSD  
Wayne Springer, Ph.D., Chief of Environmental, Health and Safety, VA San Diego  
Heathcare System

Additional meeting attendees were introduced:

Tom Evans, M.D., Executive Dir. of Infectious Diseases Clinical Research, Vical  
William H. Cover, Regulatory Affairs Associate Director, Vical

Meeting Opening – Dr. William Cover

Brief commentary of concerns regarding BSL-II activities within Clinical Trial Material/Commercial Manufacturing Center was addressed. W. Cover stated that the Pacific Center Court building is run differently from universities and other research laboratories, as Vical must address issues including personnel flow and keeping research materials separate from manufacturing. A priority of Vical is to ensure that there is no cross contamination of GMP materials.

Voting members were provided with a copy of the *Air Pressurization/Room Classification – 2<sup>nd</sup> Floor (floor plan)* and the CV of Kristin R. Carner.

**II. Tour of Vical Incorporated**

Tour of Vical's new facility at 10390 Pacific Center Court – Anita Green

A. Green presented a slide of the Air Pressurization/Room Classification – 2<sup>nd</sup> Floor and spoke in detail about the BSL-II Laboratory. She gave the Vical IBC members a tour of the PCC 2<sup>nd</sup> facility.

**III. Meeting Objectives – Anita Green, IBC Chairman**

Anita Green called for a vote to the following proposal:

1) Kristin R. Carner as a new IBC Voting Member to replace Phillip Ramsey.

Vote: Unanimous (4/4 present voting members) for proposal 1.

2) Approval to use the BSL-II Laboratory on the second floor for experiments involving BSL-II materials.

Vote: Unanimous (4/4 present voting members) for proposal 2.

W. Springer initiated discussion of restrictions. He stated his concern if Vical were to modify expression of a [redacted] change the host range, and/or pseudotyping of the [redacted] T. Evans replied that Vical's research does not include those listed and if Vical were to pursue any studies involving those mentioned that a different company would be doing those studies. W. Cover assured the IBC members that Vical uses [redacted] shown in the [redacted] Study. Vical stated that should any new studies relevant to these restriction an IBC meeting will be scheduled to discuss the issue(s).

T. Evans stated that the following challenges are performed as listed below:

- [redacted]
- [redacted]
- [redacted]
- [redacted] (probably irrelevant)

3) Vical Biosafety Officer authority to review/approve BSL-II activities and designated areas within Vical facilities with the exception that IBC meeting be held for

Vote: Unanimous (4/4 present voting members) for proposal 3.

W. Springer initiated discussion of restrictions. He vocalized his concerns that an IBC meeting should be scheduled if Vical were to:

- Modify expression of a toxin
- Change the host range
- Perform pseudotyping of [redacted]

T. Evans replied that Vical's research does not include those listed and if Vical were to pursue any studies involving those mentioned that a different company would be performing the studies. Vical agreed that should any new studies relevant to these restriction an IBC meeting will be scheduled to discuss the issue(s).

Anita was given confirmation from the other IBC voting members that she is authorized to review/approve.

**IX. Adjournment**

Anita Green adjourned the meeting at 1:45 p.m.

W. Cover thanked the IBC members for their attendance and outstanding duration with Vical.

Minutes submitted by Michelle Yu, RA Associate, Vical.IBC meeting minutes

Submitted by: Michelle Yu, Michelle Yu, IBC Administrator

Reviewed and Accepted by: Anita Green, Anita Green, IBC Chairperson

A draft of the meeting minutes will be [REDACTED] to [REDACTED]

**Vical IBC Meeting Minutes**  
Meeting held on December 14, 2004

**COPY**

**I. Call to Order and Administrative Issues**

The meeting was called to order by chairman, Anita Green at 11:00 a.m.

Introduction of IBC Members –Anita Green

IBC Chairman: Anita Green (voting member), Safety Manager, Vical  
IBC Administrator: Michelle Yu (non-voting member), Regulatory Affairs Associate,  
Vical

Voting members of IBC in attendance:

Anita Green, Chairperson, Biosafety Officer, Vical  
Gretchen Jimenez, Ph.D., Research Scientist, Vical  
Brenda Wong, Biosafety Officer, UCSD  
Wayne Springer, Ph.D., Chief of Environmental, Health and Safety, VA San Diego  
Heathcare System

Additional meeting attendees were introduced:

Tom Evans, M.D., Vice President of Infectious Diseases Clinical Research, Vical  
Zeny Ortega, Quality Assurance, Associate Director, Vical

Meeting Opening – Anita Green

Anita presented a slide of the BSL-II Laboratory at 9373 Towne Centre Dr. She gave a brief update on the new additions to the facility.

Voting members were provided with a copy of CV for nominated voting member.

**II. Meeting Discussions**

Zeny updated the IBC on the recent FDB inspections. The inspectors found no major observations and upon receipt of the license, the Pacific Center Court facility will be licensed as a distributor of manufactured products. Vical will ship clinical material from the PCC facility.

Tom presented summaries of current clinical trials sponsored by Vical. This included SAEs reported to NIH for the Allovectin-7 product.

**III. Meeting Objectives – Anita Green, IBC Chairman**

Anita Green called for a vote to the following proposal:

1) Gretchen S. Jimenez, Ph.D. as a new IBC Voting Member to replace Catherine Luke, Ph.D.

Vote: Unanimous (3/3 present voting members) for proposal 1.

**IX. Adjournment**

Anita Green adjourned the meeting at 12:00 p.m.

Anita thanked the IBC members for their attendance and outstanding duration with Vical.

Minutes submitted by Michelle J. Yu, RA Associate, Vical.IBC meeting minutes

Submitted by: Michelle Yu, Michelle Yu, IBC Administrator

Reviewed and Accepted by: Anita Green, Anita Green, IBC Chairperson

**COPY**

**Vical IBC Meeting Minutes**  
Meeting held on 6 October 2005

**I. Call to Order and Administrative Issues**

The meeting was called to order at 11:30 a.m.

Introduction of IBC Members –Anita Green

IBC Chairman: Anita Green (voting member), Safety Manager, Vical  
IBC Administrator: Michelle Yu (non-voting member), Senior Regulatory Affairs Associate, Vical

Voting members of IBC in attendance:

Anita Green, Chairperson, Senior Regulatory Affairs Associate, Vical  
Gretchen Jimenez, Ph.D., Research Scientist, Vical  
Kris Carner, Assay Development Manager, Vical  
Brenda Wong, Biosafety Officer, UCSD  
Wayne Springer, Ph.D., Chief of Environmental, Health and Safety, VA San Diego  
Heathcare System

Additional meeting attendees were introduced:

William Wood, Biosafety Officer, Vical  
Ed Domanico, Director, Facilities

Meeting Opening

An overview of the new employee safety training and spill procedures was presented.

Voting members were provided with a copy of CV for nominated voting member.

**II. Meeting Discussions**

The new BSL-2 Laboratory Room that was built at 10390 Pacific Center Court, was subsequently reconfigured and is now being used as a clean room. Currently there are no BSL-2 activities at the Pacific Center Court facility. The BSL-2 Laboratory at 9373 Towne Center Drive is being used for small quantities in the isolation, prep and freezing of serum and cells for spot assay and PBMC activities.

The IBC was given a tour of the manufacturing facility.

**III. Meeting Objectives – Anita Green, IBC Chairman**

The IBC voted on the following proposal:

1) William (Bill) Wood as the new IBC Chairperson, Voting Member to replace Anita Green

Vote: Unanimous (4/4 present voting members) for the proposal.

**IX. Adjournment**

The meeting was adjourned at 1:00 p.m.

The IBC members were thanked for their attendance and outstanding duration with Vical.

Minutes submitted by Michelle J. Yu, Senior RA Associate, Vical IBC Administrator

Submitted by: Michelle Yu 19 Oct 05, Michelle Yu, IBC Administrator

Reviewed and Accepted by: William Wood, William Wood, IBC Chairperson  
19 Oct 05