

November 1, 2006

Edward Hammond
The Sunshine Project
1920 Stuart St.
Berkeley, CA 94703

PM
11/07



RE: Request for Vaxin's IBC Minutes

Dear Mr. Hammond,

Pursuant to your request dated October 11, 2006, re-dated October 12, 2006, and faxed October 13, 2006, the minutes of Vaxin's Institutional Biosafety Committee are attached. Please note that the address for Vaxin shown on your request is significantly out of date. The correct address is shown below and is also available on our web site. To avoid delays in the future please correct your database to reflect this current information.

Vaxin's IBC was established in October of 2005, was confirmed to us in writing by the NIH in early November of that year, and held its first meeting shortly thereafter. The minutes of that first meeting were approved at the second meeting, held October 30, 2006. The approved minutes are attached. The minutes of the second meeting have not yet been approved by the committee and are therefore cannot be provided at this time. However, I can inform you that no additional protocols were reviewed or approved. They will be available after review and approval by the committee at our next meeting.

I would like to take this opportunity to point out that none of the microbes in Vaxin's labs are on the Select Agents list, nor do we have any microbes which would require BSL3 facilities. Any protocols which involve microbes fitting those descriptions refer to work done at other facilities pursuant to agreements with Vaxin. The IBC's of those facilities will also have approved protocols for the work done in their labs under those agreements. Likewise, Vaxin does not maintain any animal facilities. Any animal research is done at other facilities and approved by the required committees at the respective facilities.

Sincerely,

A handwritten signature in blue ink, appearing to read "Douglas E. Grove".

Douglas E. Grove, MBA
Secretary, Vaxin Institutional Biosafety Committee

Institutional Biosafety Committee



MINUTES

November 14, 2005

9:30 AM – 12:30 PM

OADI, Room 249

Members Present

Zhongkai Shi, MD

Kent R. Van Kampen, DVM, PhD

Edward Jex, BS

Andrew A. Webster, PhD

Robert M. Riggs, PhD

Douglas E. Grove, BS

Chair, Inst. Member

Inst. Member

Inst. Member

Non-affiliated Member

Non-affiliated Member

Secretary, Inst. Member

Members Absent

None

Visitors

None

Introduction

Chair Shi called the meeting to order at 9:31 AM. The Vaxin Institutional Biosafety Committee (VIBC) members were introduced. All members were present, thus membership constituted a quorum.

Discussion

Administrative Issues

This being the first meeting of the VIBC, no previous meeting minutes existed to be approved. Members discussed the basics of Vaxin's vectored vaccine technologies, and familiarized each other with their relative contributions to the expertise of the VIBC. The use of standardized protocol submission forms was discussed.

Approval of Protocols

0423Trent

"Replication-defective adenovirus vectored pandemic influenza virus vaccine"

This protocol indicates that vector preparation and manipulation will take place in facilities appropriate to the work to be done. Although implicit in the procedures described, for the sake of clarity the VIBC discussion resulted in the following comments:

- The H5N1 virus will be handled only in appropriately equipped BSL3/ABSL3 conditions, by personnel with appropriate training.
- Animal studies must not be initiated without approval from the IACUC of the facility where those studies will take place.
- It is recommended that animals be housed in filter top cages.

- Cage change-out is to be done in a biosafety cabinet with current certification.
- The cages and bedding from challenged animals should be autoclaved prior to cleaning/disposal.
- Waste disposal must be handled by a properly equipped/licensed/certified facility.

Motion for approval conditioned on the preceding comments was made by Dr. Van Kampen, seconded by Dr. Riggs, and approved unanimously.

0502 Tang

“Adenovirus vectored nasal anthrax vaccines”

This protocol indicates that vector preparation and manipulation will take place in facilities appropriate to the work to be done. Although implicit in the procedures described, for the sake of clarity the VIBC discussion resulted in the following comments:

- The *B. anthracis* spores will be handled only by personnel with appropriate training, and all work with that organism will be performed only in an annually certified biosafety cabinet.
- Animal studies must not be initiated without approval from the IACUC of the facility where those studies will take place, and must follow their safety guidelines for the organism(s) involved.
- It is recommended that animals be housed in filter top cages.
- Cage change-out is to be done in a biosafety cabinet with current certification.
- The cages and bedding from challenged animals should be autoclaved prior to cleaning/disposal.
- Waste disposal must be handled by a properly equipped/licensed/certified facility.

Motion for approval conditioned on the preceding comments was made by Dr. Van Kampen, seconded by Dr. Webster, and approved unanimously.

Recess

At 11:10 AM the meeting was adjourned from meeting in person. Further discussion and voting via email was held to consider the following:

Approval of Protocols

0511 Tang –

“Development of vectored influenza vaccines”

This protocol indicates that vector preparation and manipulation will take place in facilities appropriate to the work to be done. Although implicit in the procedures described, for the sake of clarity the VIBC discussion resulted in the following comments:

- Animal studies must not be initiated without approval from the IACUC of the facility where those studies will take place, and must follow their safety guidelines for the organism(s) involved.
- It is recommended that animals be housed in filter top cages.
- Cage change-out is to be done in a biosafety cabinet with current certification.
- The cages and bedding from challenged animals should be autoclaved prior to cleaning/disposal.
- Waste disposal must be handled by a properly equipped/licensed/certified facility.

Motion for approval conditioned on the preceding comments was made by Dr. Van Kampen, seconded by Mr. Grove, and approved unanimously.

Administrative Recognition

The Chair made administrative recognition of a protocol currently operating under approval by an outside IBC:

0500 Tang

“Vaccination by Topical Application of Recombinant Vected Vaccines”

In recognition of the expertise and experience of the UAB IBC the Chair made note of the existing approval and its comments as follows:


- This approval follows a previous approval by the UAB IBC under project number 01-014 on 10-16-02 with the comments below.
 - It is recommended that animals be housed in filter top cages.
 - The Animal Resources Program should be consulted prior to project initiation for instruction on animal space allocation.
 - All work with *B. anthracis* spores should be performed in an annually certified biosafety cabinet.
 - Cage change-out should be done in an annually certified biosafety cabinet.
 - The cages/bedding from challenged animals should be autoclaved prior to cleaning/disposal.
 - OH&S should be contacted prior to project initiation for guidance on waste disposal issues.
 - Section 5.5, Restricted Research Activities, of the UAB Biosafety Manual, must be satisfied.
- The Chair administratively accepted their approval of this ongoing research as a grandfathering approval for this protocol.

Adjourn

The meeting was closed at the conclusion of the email voting.


Next Meeting

The next meeting will be held when called and will be scheduled for a date, time and venue agreeable to all committee members.

 10-30-06

Zhongkai Shi, MD
Chairman, VIBC

Date

 10/30/06

Douglas E. Grove, MBA
Secretary, VIBC

Date