UMDNJ
ROBERT WOOD JOHNSON MEDICAL SCHOOL
University of Medicine & Dentistry of New Jersey

Office of Research and Sponsored Programs

March 26, 2007

Edward Hammond,
The Sunshine Project
1920 Stuart Street
Berkeley, CA 94703

Dear Mr. Hammond:

We apologize for not being able to fulfill the Sunshine Project's request, for our institution's Institutional Biosafety Committee (IBC) meeting minutes, in a more timely fashion.

The individual responsible for providing the documentation and to whom the request was directed to, Mr. Joseph Broderick, is no longer associated with UMDNJ-Robert Wood Johnson Medical School. Due Mr. Broderick's departure from the University, his duties are in the process of being assumed by other individuals within the department.

As requested in your letter, to UMDNJ-Robert Wood Johnson Medical School, dated October 11, 2006, please find enclosed the meeting minutes for the time period from May 1, 2003 to the present. Please note, that the minutes have been redacted to remove the names of IBC Committee Members and Investigators.

Again, please accept our sincerest apologies for the delay in fulfilling this request.

Sincerely,

Christopher M. Stastny
Business Systems Analyst

Cc: Joseph Dougherty, PhD, Institutional Biosafety Committee Chair
Scott Finkernagel, MS, CBSP, Biological Safety Officer
Judith A. Neubauer, PhD, Associate Dean for Research

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
May 11th, 2006

Members Present

Joseph Broderick, Joseph Dougherty, Scott Finkernagel, Yacov Ron, Ellen Welch, Iris Udasin, Patricia Sonsalla, Tomas Smith, Joseph Bertino

I. Approval of meeting minutes

Joseph Broderick provided meeting minutes for IBC committee meetings dated 3/25/2004, 5/20/2004, 9/30/2004, 1/20/2005, 6/16/2005, 7/21/2005, 1/19/2006. All minutes were approved.

II. New Human Gene Therapy Trial:

The EBC reviewed a summary prepared by the Biological Safety Officer, Mr. Finkernagel, for [redacted] "Phase II study of PROSTVAC-V (Vaccinia)/TRICOM and PROSTVAC-F (Fowlpox)/TRICOM with GM-CSF in Patients with PSA Progression After Local Therapy for Prostate Cancer" Version Date: February 3, 2006 protocol. The Summary included study objectives, agents, treatment schedule, adverse events, reporting of adverse events and biosafety considerations. Study was discussed and approved with recommendations at BSL-2.

III. Review of RDNA Submissions:

The committee reviewed summaries, prepared by the Biological Safety Officer, Mr. Finkernagel, for the following RDNA submissions.

1. [redacted], B06-0003, Approved @ BL-2 Safety and Handling of retroviruses and transfected cells. (2/8/2006)
2. [redacted], B06-0004, Exempt from NIH Guidelines; Approved at Biosafety Level I
3. [redacted], B06-0005, Exempt from NIH Guidelines; Approved at Biosafety Level I
4. [redacted]., B06-0006, Exempt from NIH Guidelines; Approved at Biosafety Level I
5. [redacted], B06-0007, P06-0008, Approved @ BSL-2+ consistent with Lentiviral SOP
6. [redacted], B06-0008, P06-0009, Approved @ BSL-2+ consistent with Lentiviral SOP

IV. Pathogen Registrations:

The committee reviewed and approved the following pathogen registrations at the biosafety level indicated.

Protocol Number	Principal Investigator	Organism	Biosafety Level
P06-0001	[redacted]	HU-Cell Lines	2
P06-0002	[redacted]	Neisseria Gonorrhoeae	2
P06-0003	[redacted]	HU-Cell Lines	2
P06-0004	[redacted]	HU-Cell Lines	2
P06-0005	[redacted]	Mycoplasm pulmonis	2
P06-0006	[redacted]	HU-Cell Lines	2
P06-0007	[redacted]	Candida Albicans	2
P06-0008	[redacted]	Lentiviral Vector	2+
P06-0009	[redacted]	Lentiviral and FIV Vectors	2+

V. New Business:

1. The committee reviewed and approved 3 high school student proposals with the following stipulations:
   - A trained adult would be present at all times
   - The student would not work with infectious agents
   - The student would not work with primary cell or tissues
   - Form should be properly filled out and stipulations are adhered to.
2. The committee discussed the request received by the Research Office for meeting minutes from the Sunshine Project. Mr. Finkernagel provided a guidance letter from T4M-OBA, "Questions and Answers Concerning IBC Meeting Minutes". The committee recommended that the Research Office forward this request to the Legal Department and let the Legal Department appraise them on how to proceed with this request.
3. The committee recognized the receipt of a LETTER NOTIFYING IBC TERMMATION OF [redacted] HGT STUDY: "A Phase III Randomized Controlled Study to Evaluate the Safety and Efficacy of PANVACTM-VF in Combination with GM-CSF versus Best Supportive Care or Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas Who Have Failed a Gemcitabine-Containing Chemotherapy Regimen"

VI. Meeting Adjourned

The meeting was adjourned at 5:45pm.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
January 19, 2006

Members Present:

Joseph Dougherty (Chair), Joseph Broderick, Scott Finkernagel, Judith Neubauer, Pat Sonsalla. Iris Udasin, Ellen Welch

I. Recombinant DNA Protocols

1. **B05-0010, [redacted], Pharmacology, "RAN G-quadruplexes as Novel Anti-Cancer agents for Breast Cancer"**

   Summary: Introduction of RNA G-quadruplexes into xenografted human breast cancer cell lines in nude mice.

   The Committee reviewed this protocol and approved it at Animal Biosafety Level 2.

2. **B05-0011, [redacted], CINJ-Pharmacology, "MDR1 Enhancesomes and p53 transcriptional repression studies"**

   Summary: Eukaryotic expression vectors transfected into human cells in culture. Exempt from rDNA guidelines

   The Committee reviewed this application and approved it. Human cells and recombinants at will be handled at BL-2.

3. **B05-0012[redacted], Surgery, "Emap II regulation of pulmonary cell proliferation"**

   Summary: Emap II , an anti-angiogenic protein, will be expressed on pAdEasy vector and transfected into Ad 293 cells to produce recombinant adenovirus.

   The Committee reviewed this application and approved it at Biosafety Level 2 and contingent on following UMDNJ SOP for adenoviral vectors.

4. **B05-0013, [redacted], Surgery, "Immuno-gene therapy for prostate cancer based on transforming growth factor-beta insensitive macrophages"**

   Proposal to use a murine stem cell virus vector to transduce human and murine cells.

   The Committee reviewed this application. It was approved at BL-2 contingent on [redacted] being made aware that the vector could go into humans and care should be taken with the growth factor.

5. **B06-0001, [redacted], M.D., Ph.D., "Cloning and Expression of Modified Tau Protein"**

   Exempt rDNA protocol (rDNA in tissue culture E. coli host vector system).

   The Committee reviewed this application and approved it at BL-1.

6. **B06-0002, [redacted]., "Molecular mechanism of regulation of contraction; regulation of contraction in muscle and non-muscle; dynamics of the cytoskeleton during gliosis of astroctes"**

   This protocol was just received on Monday. Mr. Finkernagel has not yet had time to inspect the lab and facilities. It was approved at BSL2 with SOP for adenoviral vectors and contingent on a satisfactory inspection of [redacted] facilties.

II. Pathogen Registries

The following pathogen registries were received.

Protocol No.	Principal Investigator	Organism (s)	Source/Strain	Biosafety Level
P05-0009	[redacted]	Hu-Cell lines	ATCC # mda-mb 435	2
P05-0010	[redacted]	Hu-Cell lines	mcf, mda, dld,ht, bt,hct	2
P05-0011	[redacted]	Adenoviral Vector & Hu-Cell lines	pAd-easy (Ad-5) stratagene	2
P05-0012	[redacted]	Streptococcus & human tissue	ATCC #49446 agalactiae, placental	2
P05-0013	[redacted]	Hu-Cell lines	Prostate cell lines	2
P05-0014	[redacted]	Hu- Cell lines	Neuroendocrine	2

III. New Business

1. Mr. Finkernagel reviewed a serious adverse event (SAE) in [redacted] study. The SAE was reported as fever (pyrexia) and occurred at another site. The SAE was deemed to be possibly related to study drug administration. The Committee took note, but did not feel any further action was warranted.
2. Mr. Finkernagel distributed the revised Guidelines for Sorting of Unfixed Cells. He reported that the revised policy represents standard practice. [redacted] and [redacted] both provided comments. It was noted that the cell sorter at EOHSI and the one in [redacted] lab do not have containment. In the department of Surgery, there is containment but the company will not guarantee it. Mr. Finkernagel recommended that it be tested for efficacy.

   This policy also contains a form which must be filled out prior to using the cell sorter. Some suggestions were made to make the form easier to use. The Committee accepted the policy as written and will require that anyone using a cell sorter will have to adhere to the guidelines, fill out the form, and have it reviewed by the Biosafety Officer. Any cell sorting of human or primate cells will require the Biosafety Officer's prior approval. It was emphasized that [redacted] sorter cannot be used for unfixed human or primate cells.

IV. Meeting Adjourned

The meeting adjourned at 4:55 p.m.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
July 21, 2005

Members Present:

Joseph Bertino, Joseph Broderick, Scott Finkernagel, Patricia Sonsalla, Iris Udasin

I. Gene Therapy Trial

The Committee met solely to consider "A Phase I Study of Intravesicle Recombinant Fowlpox-GM-CSF (rF-GM-CSF) and/or Recombinant Fowlpox-TRICOM (rF-TRICOM) in patients with Bladder Carcinoma Scheduled for Cystectomy." ([redacted] and [redacted]). This protocol had received approval from the National Cancer Institute on June 21, 2005 and had received a letter from the IRB on July 11, 2005 approving the project with minor amendments. Mr. Finkernagel reminded the committee that recruitment for this project went on hold in October or November of 2004 in response to a serious adverse event. The protocol was revised and the version under consideration by the Committee was the 4/26/05 revision.

The Committee felt that the revisions addressed the concerns raised by the serious adverse event by including in exclusion criteria those with liver function abnormalities, additional monitoring for AST/ALT, reducing the escalation schedule and adjusting the consent document.

The Committee agreed to approve the study as revised. Mr. Finkernagel will draft a letter informing the investigator of Committee approval. In addition, the investigator will be reminded of the need to report serious adverse events to the IBC and will be asked to inform the IBC when study accrual is re-established and when it concludes. The investigator will also be reminded of the need to resubmit the protocol for IBC review if significant changes are made.

II. Adjournment

The meeting adjourned at 3:45 p.m.

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Institutional Biosafety Committee Meeting
Minutes
June 16, 2005

Members Present

Joseph Dougherty (Chair), Joseph Broderick, Scott Finkernagel, Judith Neubauer, Thomas Smith, Pat Sonsalla

I. Gene Therapy Trials (annual updates)

The human gene therapy trials of the following investigators were reviewed at the meeting.

A. [redacted], "Phase II Randomized, Double-blind, controlled study to evaluate the safety and efficacy of Prostvac-VF/Tricom in combination with GM-CSF in patients with Androgen-Independent Adenocarcinoma of the Prostate."

This study requires annual re-approval. The discussion focused on an adverse event that occurred in the study that required a study subject to be hospitalized. The Committee felt that, since the last dose of the study drug was administered almost a month before the hospitalization that the incident was unlikely to be related to the study drug. Mr. Finkernagel will continue to ensure that the IBC gets notified immediately of serious adverse events. The study was approved to continue.

B. [redacted], "A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ad5FGF-4 in Patients with Stable Angina (AGENT-3)."

[redacted] noted that enrollment was halted in this study on January 31, 2004. At our site, four people had received the study drug, but one withdrew from the study, so three remain. Several serious adverse events occurred, but none were felt to be related to the study drug. In the past, concern had been raised on the Committee about the growth factor paired with vaccinia. Dr. Neubauer requested that a summary of the previous discussion be prepared and provided to the Committee members.

C. [redacted], M.D., "A Phase III Randomized, Controlled Study to Evaluate the Safety and Efficacy of PANVACTM-VF in Combination with GM-CSF Versus Best Supportive Care or Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas Who Have Failed a Gemcitabine-Containing Chemotherapy Regimen."

One patient is currently enrolled at our site, and four more are expected to be recruited. One serious adverse event occurred in March, but the patient was enrolled in the placebo arm, so it was not related to the study drug. At another site, a patient experienced dyspnea and respiratory failure ending in death, but these events were determined to be related to disease progression. The study was approved.

D. [redacted]

This is an NCI sponsored Phase I study that continues until the bladder is removed. Due to adverse events, Phase I will be repeated. This study is currently on hold. The Committee stated that when the study activates, the Committee will be notified and we will discuss our concerns for this study. If [redacted] receives approval to resume the study, the IBC must discuss and approve the study prior to its resumption and subject to IRB approval.

II. Recombinant DNA protocols

1. **B05-0002, P05-0001, [redacted], "mTOR Signal Transduction"**

   The Committee reviewed this application and approved it at BSL2+.

2. **B05-0003, [redacted], "Histone deacetylation in oligiodendrocyte differentiation/Gender-specific role of p53 in remyelination."**

   The Committee reviewed this application and approved it at BSL2 and following guidelines on safety and handling of retroviruses.

3. **B05-0004, [redacted], "Histone deacetylation in oligiodendrocyte differentiation and lentiviruses/Gender-specific role of p53 in remyelination and lentiviruses."**

   The Committee reviewed this application and approved it at BSL2+ contingent upon inspection of facilities.

4. **B05-0005, [redacted], "Introduction of recombinant DNA into the mouse embryo."**

   The Committee reviewed this application and approved it at Animal Biosafety Level 1.

5. **B05-0006, [redacted], "Therapies for Lysosomal Storage Disease" ,**

   The Committee reviewed this application and approved it at Animal Biosafety Level 1.

6. **B05-0007, [redacted], "A Gene Therapy Approach for the Treatment of EAE",**

   The Committee reviewed this application and approved it at Animal Biosafety Level 1.

7. **B05-0008, [redacted], "Mouse gene targeting and tissue collection"**

   The Committee reviewed this application and approved it at Animal Biosafety Level 1.

8. **B05-0009, [redacted], "Molecular mechanisms of mammalian organ development"**

   The Committee reviewed this application and approved it at Animal Biosafety Level 1.

III. Pathogen Registries

The following pathogen registries were received.

Protocol No.	Principal Investigator	Organism (s)	Source/Strain	Biosafety Level
P05-0001	[redacted]	Lentivirus/ Human cells	Invitrogen pLL3.7 (MIT)	2+
P05-0002	[redacted]	HU-CELLS-CORD/MARROW	CELGENE	2

Protocol No.	Principal Investigator	Organism (s)	Source/Strain	Biosafety Level
P05-0003	[redacted]	Ureaplasma urealyticum/hu cells	ATCC # 27813	2
P05-0004	[redacted]	Gardnerella vaginalis/ hu cells	ATCC # 55195/ Human isolates	2
P05-0005	[redacted]	HU-BLOOD	Patient(s)	2
P05-0006	[redacted]	Hu-Cell lines	CF lines	2
P05-0007	[redacted]	Human materials	Patient(s)	2
P05-0008	[redacted]	Escherichia coli/LPS	J5, O55:B5	2

IV. New Business

1. Mr. Finkernagel distributed for comment a copy of the Procedure for Loss of Water and/or Supplied Water is not Potable, a part of the University's disaster plan.
2. Mr. Finkernagel also distributed Guidelines for Sorting of Unfixed Cells. This policy is important because cell sorters are presently used at the Medical School and may be used to sort patient samples. If those samples are not fixed, and the sorter is used without containment, biosafety requirements cannot be met. The containment unit for a cell sorter may cost around $25,000. Mr. Finkernagel gathered guidelines from other schools and extracted pertinent material from the journal Cytometry to develop these guidelines. Dr. Neubauer suggested that the material be reorganized for clarity and that material extracted from published sources be properly attributed.

V. Adjournment

The meeting adjourned at 5:50 p.m.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
January 20, 2005

MEMBERS PRESENT:

Joseph Dougherty (Chair), Joseph Broderick, Scott Finkernagel, Yacov Ron, Patricia Sonsalla, Iris Udasin, Ellen Welch

1. Approval of minutes

During a review of the records of the IBC, it was discovered that the minutes for the meetings of November 20, 2003; December 18, 2003; and May 20, 2004 had not been approved. The minutes were distributed prior to the meeting for review. At the meeting, these three sets of minutes were approved unanimously.

The minutes of the previous meeting September 30, 2004 were not approved and were to be revised and presented at the next meeting of the IBC.

2. Gene Therapy Trial

CINJ- Bladder Carcinoma Study, rFowlpox- GM-CSF-TRICOM

The amendments sent out for review—change in PI from [redacted] to [redacted] and a slight change in the title were approved unanimously through an email poll of the committee. Because of the adverse events during last summer, there will be more amendments to the study, including a change in the consent form and changes in the dose schema as discussed in the September meeting.

3. Recombinant DNA protocols (see attached summaries)

B04-0020, [redacted] Dept. of Biochemistry, 12/16/2004

"Targeting Hematopoietic Stem Cells for Cancer Therapy".This non-exempt protocol was approved at BL-2

B05-0001, [redacted], CABM/Biochemistry, 01/19/2005

"Functional analysis of the v- and c-Rel oncoproteins", This non-exempt protocol was approved at Animal Biosafety level 2

4. Pathogen Registries

P04-0027, [redacted] vaccinia virus, ATCC #VR-1354

Conditionally approved 12/20/2004, subject to approval of committee. The Committee discussed the importance of ensuring that all who work with vaccinia are not in any risk categories and have no contradindications. The Committee also stressed the importance of making sure all lab personnel had completed blood-borne pathogen training.

The following pathogen registries, both for human cell lines, were also received.

Protocol Number	Principal Investigator	Organism (s)	Strain_ID	Biosafety Level	Source
P04-0025	[redacted]	HU-Cell Lines	Multiple	2	ATCC/NIH
P04-0026	[redacted]	HU-Cell Lines	Multiple	2	ATCC

5. Announcements

1. Mr. Finkernagel announced that the 2004-2005 bloodborne pathogens and biosafety online training module is available at the following URL: http://www2.umdnj.edu/eohssweb/publications/2004Bio.htm
2. The NIH sent out a notification to all Institutional Biosafety Committees on December 6 reminding them about registration with the Office of Biotechnology Activities, annual renewals of registrations and the possibility of site visits.
3. Mr. Finkernagel announced that SOPs are available online on the EOHSS website for **lentivirus:** http://www2.umdnj.edu/eohssweb/publications/LentivirusSOP.pdf **adenovirus:** http://www2.umdnj.edu/eohssweb/publications/AdenovirusSOP.pdf

6. Adjournment

The meeting adjourned at 5:06 p.m.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
September 30, 2004

MEMBERS PRESENT: Joseph Bertino, Joseph Broderick, Joseph Dougherty, Scott Finkernagel, Yacov Ron, Thomas Smith, Patricia Sonsalla, Iris Udasin, Ellen Welch

I. Serious adverse events (July, August, September) in Gene Therapy Trial

CINJ- Bladder Carcinoma Study, rFowlpox- GM-CSF-TRICOM PI: [redacted], MD

1. *Patient F-K/003*
2. *Patient V-L/004*
3. *Patient R-B/007*

See attached summary and adverse events reports.

Discussion: It was noted that all three patients were at the first dose level of the study; one was in Arm A (rF-GM-CSF) and two were in Arm B (rF-TRICOM). The Committee wanted first of all to make sure that the investigators were aware of the reporting requirement to NIH and the FDA regarding serious adverse events (SAE). Dr. Dougherty noted that one of the two on Arm B was seriously ill. One Committee member asked whether this was a multicenter study and whether similar reactions occurred at other sites. The Committee felt that the investigators should notify all study participants of the SAE and amend the consent form to include mention these possible adverse reactions. Finally, a question was raised about whether the protocol was changed to reflect the modified dosing.

II. New Human Gene therapy trial at CINJ

"A Phase III Randomized, Controlled Study to Evaluate the Safety and Efficacy of PANVAC™-VF in Combination with GM-CSF Versus Best Supportive Care or Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas Who Have Failed a Gemcitabine-Containing Chemotherapy Regimen"

This protocol was submitted on August 11 and forwarded to Research office for distribution to committee members. See attached summary. Mr. Finkernagel informed the committee that this Phase III trial has an FDA IND number and that the NIH RAC will not review this protocol.

The Committee agreed with the recommendations of the Biosafety Officer in his summary (attached). In addition, Mr. Finkernagel said that he would make sure that he was notified of adverse events and would inform the appropriate committee members if they occur. Mr. Finkernagel reported that the IRB had raised the question of whether employees and family members of study participants should be offered immunization to vaccinia. The Committee recommended that the provision of immunizations should be discussed with employees and family members and offered if they wanted it.

Dr. Dougherty moved approval of the protocol and the Committee unanimously approved it.

III. Acrylamide Splash Incident

In July, a high school student working in [redacted] lab dropped an uncapped centrifuge cup and splashed acrylamide into his eye. He was not wearing eye protection and he was not being supervised at that moment. He had done the procedure before. He flushed his eyes, was seen by the physician at Employee Health and was referred to an ophthalmologist. The student is not expected to experience any problems as a result of the incident.

The incident prompted EOHSS to draft Guidelines for Supervising a High School Student in a UMDNJ-RWJMS Laboratory. These Guidelines were given to the Committee for review and comment. Some members of the Committee felt that having high school students in the labs was a potential danger to the students and a large potential legal liability. The Committee felt that the Research Office needs to be made aware of this liability. Some felt that, if high school students were to be in RWJMS labs at all it should be under a more structured format and with more thorough training.

IV. Brief review of rDNA submissions

1. B04-0014, [redacted] CABM/Pediatrics, Lentiviral vectors in tissue culture, ***non-exempt, BL2+*** (see attached summary)

   Mr. Finkernagel reported that he had inspected [redacted] lab and had trained his lab staff on the use of lentiviral vectors. The Committee reviewed his recommendations (attached summary) and approved the work at BSL-2+.
2. B04-0015, [redacted] CABM/Medicine, Adenoviral vector in mouse tissue and mice (future), ***non-exempt, BL-2*** (see attached summary)

V. Brief review of Pathogen registries

The Committee acknowledged receipt of the following pathogen registries:

Protocol #	Principal Investigator	Organism (s)	Strain_ID	Biosafety Level	Source
P04-0018	[redacted]	HU-CELL LINES	mda mb-231	2	ATCC
P04-0019	[redacted]	HU-CELL LINES	HEK 293	2	ATCC
P04-0020	[redacted]	Chlamydia trachomatis	VR-123 (nigg)	2	ATCC
P04-0020	[redacted]	Chlamydia trachomatis	VR-1477(serovar C)	2	ATCC
P04-0021	[redacted]	HU-CELL LINES	HEK 293, T, MRC, RH30	2	ATCC
P04-0022	[redacted]	Lentivirus/ Human cells	ES cells	2+	MIT
P04-0023	[redacted]	ADENOVIRUS	Ad.5	2	U of Iowa
P04-0024	[redacted]	HU-CELL LINES	Hela, KB, SW 620, SK-N-AS, Hep G2, H1080	2	ATCC/NIH

VI. New Business

1. **2004 Bloodborne pathogens and biosafety online training module**

   Mr. Finkernagel announced that the 2004 Bloodborne pathogens and biosafety online training module is now available for review. Link is: http://www2.umdnj.edu/eohssweb/eohss_bbp04/ShippingUpdates/01biosafety-faafocus.htm

   1. LOGIN User Name: [redacted]
   2. Password: [redacted]
   3. 8 sections: Bloodborne Pathogens, Modes of Disease Transmission, Work Practices and Control Methods, Prevention, Hepatitis B Vaccination, Emergencies, Biosafety updates

VII. Adjournment

The Committee adjourned at 5:20 pm.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
May 20, 2004

MEMBERS PRESENT: Joseph Dougherty (Chair), Joseph Bertino, Joseph Broderick, Scott Finkernagel, Yacov Ron, Thomas Smith, Patricia Sonsalla, Iris Udasin, Ellen Welch

I. Approval of Minutes

Dr. Bertino moved approval of the minutes of the March 25 meeting. Dr. Dougherty seconded the motion and the minutes were approved unanimously.

II. New Business

Mr. Finkernagel reported that the federal Department of Health and Human Services has created a National Science Advisory Board for Biosecurity (NSABB) to improve biosecurity measures for "dual use" materials, that is material used in legitimate biological research that could be misused to threaten public health or national security. These are largely infectious agents. Of particular concern is research that:

Would demonstrate how to render a vaccine ineffective
Would confer resistance to therapeutically useful antibiotic or antiviral agents
Would enhance the virulence of a pathogen or render a non-pathogen virulent
Would increase transmissibility of a pathogen
Would alter the host range of a pathogen
Would enable the evasion of diagnostic/detection modalities
Would enable the weaponization of a biological agent or toxin

Tracking "dual use" research is under the purview of the IBC. Mr. Finkernagel noted that the recombinant protocol forms would need to be updated to track this type of research.

III. Recombinant DNA submissions

There are 5 recombinant DNA protocols to consider at this meeting, all using replication-incompetent lentiviral vectors. Summary sheets are attached. The protocols are:

- B04-007 [redacted], Pharmacology, Invitrogen lentiviral vector
- B04-008 [redacted], Biochemistry, MLV derived FLV envelope, HIV vector
- B04-009 [redacted], Biochemistry, FLV env, FIV vector
- B04-010 [redacted] Neurology. Invitrogen lentiviral vector
- B04-011 [redacted], Neurology, Invitrogen lentiviral vector

The Committee approved all these protocols unanimously, subject to the recommendations contained in the summaries (attached).

The Committee also agreed unanimously that in the future, the standard use of lentiviral vector will be approved by the Biological Safety Officer and the Chair of the IBC temporarily. These items will then be brought to the attention of the Committee for review. Dr. Sonsalla asked if this procedure was covered by the Guidelines. The Committee felt that there is a well-established protocol for research using lentiviral vectors, but that anything unusual would be brought before the Committee prior to the initiation of research.

IV. Adjournment

The meeting adjourned at 5:20 p.m.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
March 25, 2004

MEMBERS PRESENT: Joseph Broderick, Joseph Dougherty, Scott Finkernagel, Thomas Smith, Patricia Sonsalla, Iris Udasin, Ellen Welch

1. Approval of Minutes

Dr. Sonsalla moved the approval of the minutes of the February 19, 2004 meeting of the Committee. Mr. Finkernagel seconded the motion and the minutes were approved.

2. High School Students in the Labs

Of the four high school students who have completed the paperwork to work in the labs, three will be working with human cell lines, one will be doing light microscopy. All four will be 16 years old when they begin in the lab, have had a hepatitis vaccine, have parental approval. All will require initial lab safety training, bloodborne pathogen training, radiation safety and on-going biosafety training. Mr. Smith noted that parental approval was very important and that the students cannot be unsupervised in the lab at any time. Supervision could be provided by a graduate student or a postdoc. Dr. Dougherty felt that the proposal form for high school students to work in the lab should include a statement that a trained adult will be present with the student at all times. Further, the form should say that the student will not be working with infectious agents and will not be using primary cell lines. The Committee felt that if these conditions were met--that [redacted] and [redacted] signed off that (1) a trained adult would be present at all times; (2) that the student would not work with infectious agents; and (3) that the student would not work with primary cell lines—that Mr Finkernagel and Dr. Dougherty could approve these three students.

3. [redacted] Prostvac/Tricom protocol

This protocol was designed to stimulate the immune system to attack prostate cancer cells. In Phase I, there was one serious adverse event, in March 2003, but it was not due to the study product. Phase II will add granulocyt-macrophage colony stimulating factor (GM-CSF), a protein of the immune system approved for use in humans to increase the number of white blood cells. It is planned to enroll 120 patients with 80 receiving treatment and 40 receiving the vector without the GM-CSF.

The Committee expressed some concern about the increase in doses (six doses in 140 days in Phase II versus one dose and a fowlpox booster in Phase I) and the addition of GM-CSF. The Committee felt that study personnel must be highly sensitive to untoward immune responses, including hives, difficulty breathing, or shock. The Committee votes to approve the study, but wished to remind study personnel that the IBC must be notified immediately of any adverse events.

4. SOP for Work with Tetanus

Mr. Finkernagel presented the newly developed Standard Operating Procedure (SOP) for work with tetanus toxin. The SOP (attached) requires that all employees working with tetanus go to Employee Health for a tetanus titer. There was some discussion about whether such a titer is available. The Committee approved the SOP contingent on the test being available.

5. Tetrodotoxin in [redacted] Lab

Tetrodotoxin is used in [redacted] lab to study the effects of neuronal activity on gene transcription induced by growth factors. Tetrodotoxin is a select agent, but the amounts used in the lab are well below the CDC-defined limits required for registration. There is no SOP available for this substance at present. The Committee voted to approve its use in the [redacted] lab subject to adherence to the guidelines in the BMBL.

6. Adjournment

The meeting was adjourned at 5:40 p.m.

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University of Medicine & Dentistry of New Jersey

Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
February 19, 2004

MEMBERS PRESENT: Joseph Broderick, Joseph Dougherty, Scott Finkernagel, Yacov Ron, Thomas Smith, Patricia Sonsalla, Iris Udasin, Ellen Welch

1. **Annual Review of Berlex Gene Therapy Trial**

Mr. Finkernagel reported that the sponsor, Berlex, suspended this study in February after concluding that there was no discernible benefit to the trial, which had enrolled 380 patients nationwide. There were no adverse events related to the study product.

2. **Shiga toxin Registration**

[redacted] is working with shiga toxin in human cell lines. Shiga toxin is a select agent requiring IBC review, however the 10 milligrams being used is well below the 100 milligrams that is the threshold requiring registration with the CDC. The work with cell lines must be done at BSL-2. The shiga toxin must be stored under lock and key and a strict inventory kept.

Mr. Finkernagel informed the Committee that EOHSS has hired a consultant to develop Standard Operating Procedures (SOP) for toxins.

The Committee approved the protocol at BSL-2 with the SOP for toxins in place.

3. **Tetanus toxin protocol**

[redacted] (Neuroscience) is working with tetanus toxin, putting the toxin into cell cultures and assaying for neutroprofins. She is using very small amounts, 25 micrograms. The Committee raised several issues. First, that all lab personnel require immunity to tetanus, including inoculation if necessary. A safe dose in an immunized adult should be determined. Some questioned whether they could use the tetanus toxoid instead, as a safer alternative. The Committee felt that some scientific justification for the use of the toxin is required. Also, it is important to know the concentration and whether it is safe in the event of eye contact, inhalation, or ingestion.

4. **Pathogen Registries**

Mr. Finkernagel reported five pathogen registries in the month of January. They were from [redacted] (CABM), [redacted] (CABM), [redacted], (Molecular Genetics), [redacted] (Neuroscience) and [redacted] (Molecular Genetics).

5. **Sunshine Project**

Mr. Finkernagel reported that an organization called the Sunshine Project was contacting Institutional Biosafety Committees in the United States and requesting their minutes. Their focus is on BSL-3 and BSL-4 facilities and also those using select agents and toxins in their work. The Sunshine Project opposed research useful for the development of weapons and seek to publicize who is doing research with extremely biohazardous material as a way of discouraging that research. The issue of these requests had come up on the Biosafety listserve and the conclusion there was that the minutes covering rDNA must be provided if requested, however no information on select agents and toxins should be disclosed.

6. **Lentiviral Vector**

[redacted](Pharmacology) will be using a lentiviral vector to investigate the function of mammalian type II topoisomerases. Lentivirus is a Risk Group 3 organism requiring BSL2+ containment. Lentiviral vectors should be handled following the attached SOP. Mr. Finkernagel will do an in-service for the lab. In addition, Dr. Dougherty recommended that lab personnel take a base-line blood test before the start of the work and be retested every six months. Dr. Dougherty also recommended that [redacted]consider the use of Murine Leukemia Virus as a vector.

7. **Old Business**

[redacted]work with measles virus was discussed at the December meeting. At that time his protocol was tabled until it could be determined who on the vivarium staff had immunity to measles. Dr. Udasin reported that all but one of the vivarium staff could enter the room housing the animals infected with measles. Mr. Finkernagel said that signs would be posted as to who could enter the room. Since all of the conditions required for approval at the December meeting were satisfied, the Committee voted to approve the work.

8. **Adjournment**

Dr. Sonsalla moved that the meeting adjourn. Dr. Udasin seconded the motion and the meeting adjourned at 4:55 p.m.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
December 18, 2003

MEMBERS PRESENT: Joseph Dougherty, Joseph Broderick, Scott Finkernagel, Yacov Ron, Thomas Smith, Patricia Sonsalla, Iris Udasin

1. **Pathogen Registries**
   The committee acknowledged receipt of the following pathogen registries:

   - **P03-0017** [redacted] **(Medicine)** Antiangiogenesis in CNS tumors using monocytic cells.
   - **P03-0018** [redacted] **(Pharmacology)** Tumor suppressor genes, programmed cell death, and tumorigenesis.
   - **P03-0019** [redacted] **(Medicine)** Role of iNOS in glomerulonephritis.

2. **Recombinant DNA protocols**
   1. **B03-0011,** [redacted] **(Pharmacology)** Tumor suppressor genes, programmed cell death, and tumorigenesis (summary attached)
      All approved the recommendations of the Biosafety Officer. It was noted that the standard protocols for work with nude mice should be employed and that the knockout is tumorigenic.
   2. **B03-0012,** [redacted] **(Medicine)** Antiangiogenesis in CNS tumors using monocytic cells (summary attached).
      All approved the recommendations of the Biosafety Officer.
   3. **B03-0014,** [redacted] **(Medicine)** Role of iNOS in glomerulonephritis (summary attached)
      All approved the recommendations of the Biosafety Officer.

3. **Old Business**
   P03-0014 [redacted] **(Neurology)** Influence of HHV-6 and MV infections on induction of EAE, a model of multiple sclerosis
   This protocol had been discussed at the November meeting. At that time, the Committee tabled any action on this pathogen registry until further information could be obtained about the strain of measles virus being used. Mr. Finkernagel confirmed that this strain is the Edmonson B strain, a live attenuated virus. The strain was obtained through ATCC and was used at Maryland by [redacted].
   The Committee discussed the protocol further and decided that the following conditions will apply:
   - The animals must be housed in a quarantine chamber.
   - All who work with the virus or the animals whether in the vivarium or the lab must have evidence of measles immunity. Dr. Udasin will check on the measles immunity status of the vivarium staff. Dr. Udasin must see everyone before work begins to check for measles and Hepatitis B immunity
   - No immunocompromised people may work with the animals.
   - There must be controlled access to the animals and [redacted] must be made aware of this and enforce it.

- [redacted] should be provided a list of who can access the animals and this list should be posted. Even on weekend rotations, only those on the approved list can access the animals.
- Specific Standard Operating Procedures must be posted in the room housing the animals.

Action on this protocol was tabled until the next meeting of the IBC. Dr. Udasin recommended a health and safety training session for the affected lab and vivarium staff.

4. Adjournment

The meeting was adjourned at 5:10 p.m.

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University of Medicine & Dentistry of New Jersey

Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Draft Minutes
November 20, 2003

MEMBERS PRESENT: Joseph Broderick, Joseph Dougherty, Scott Finkernagel, Thomas Smith, Patricia Sonsalla, Iris Udasin, Ellen Welch

1. **Approval of Minutes**

It was noted that we had not approved the minutes of the August meeting at our October meeting. Mr. Finkernagel moved approval of the August 21 meeting. Dr. Sonsalla seconded and the minutes were approved with two abstentions (Dougherty and Smith, who were not present). Dr. Dougherty moved acceptance of the October minutes. Mr. Finkernagel seconded the motion and the minutes were unanimously approved.

2. **Pathogen Registries**
   1. **P03-0015,** [redacted] Human Cell Lines

      The Committee reviewed this pathogen registry. The only question was whether the study had IRB approval. If not, [redacted] should be made aware of the necessity for IRB review. Approval was conditioned on IRB approval.
   2. **P03-0016,** [redacted], Herpes Simplex 1 and 2, Human Cell Lines

      This is a study of virus-host interactions in cell lines. No animals will be used. [redacted] works in CABM and has a Level 3 facility and a class 2 Biosafety cabinet. The centrifuge is equipped with cups. The Committee votes to approve this registry.
   3. **P03-0014,** [redacted], Measles Virus, Human Herpes virus type A (HHV-6A) and Human Herpes virus type B (HHV-6B)

      [redacted] received the herpes viruses from NIH when he worked there. The measles virus came with him from Maryland, originally purchased through ATCC. All these viruses require BSL2 handling. All work should be done in a Biosafety cabinet and care should be taken with aerosols. The Committee felt that anyone--whether in the lab or in the vivarium—who is working with the measles virus should be vaccinated or have evidence of immunity to measles. Measles titers were recommended for anyone working with the virus. The Committee requested more information on the strain and, in particular, confirmation that this strain is the Edmonson strain, a vaccine strain. The Committee also requested more detail in the description of the proposed research.

      The Committee tabled action on this pathogen registry until further information could be obtained. [redacted] was not intending to begin the project immediately so the Committee had time. In the meantime, Mr. Finkernagel would develop containment standards and Standard Operating Procedures for these viruses.

3. **Recombinant DNA protocols**
   1. [redacted], request for a new gene in an approved construct--review of approved 2002 rDNA protocol submission. The 2002 protocol described a recombinant going into animals. This amendment asks for approval of a new gene in the approved vector. Some Committee members felt that the new gene could have oncogenic potential after mutagenesis. One Committee member raised animal care concerns. The Committee decided to approve the amendment, but felt that Mr. Finkernagel should discuss the hazards with the PI before the study began.

4. **New Business**
    1. Mr. Finkernagel informed the Committee that he had received a memo from [redacted] of an adverse event in his Berlex study that was unrelated to the study drug.
    2. Mr. Finkernagel informed the Committee that he had gotten a call from the Centers for Disease Control and Prevention (CDC) telling him that [redacted] had done work with poliovirus. Mr. Finkernagel informed the CDC that the poliovirus that [redacted] had was destroyed 18 months ago.
    3. Biohazard Survey: Mr. Finkernagel reported on the progress in conducting a school-wide survey of biohazards.

5. **Adjournment**
   The meeting was adjourned at 5:05 p.m.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
October 16, 2003

MEMBERS PRESENT: Joseph Bertino, Joseph Broderick, Joseph Dougherty, Scott Finkernagel, Thomas Smith, Patricia Sonsalla, Iris Udasin,

1. **Pathogen Registries**

   1. P03-0010, [redacted], Staphylococcus Aureus, Review of approval 9/19/03
      Mr. Finkernagel approved this work on September 19 at BSL2 and animal BSL2. **The Committee felt that any work with pathogens that required BSL2+ and up would require full Committee review.**
   2. P03-0011 [redacted], Lentivirus and Adenovirus
      See discussion below under Recombinant DNA protocols
      P03-0012, [redacted], Human Cell lines
      Mr. Finkernagel approved this work with human cell lines. The Committee acknowledge receipt of the registry.
   3. P03-0013, [redacted], HU-CELL LINES; Chlamydia trachomatis: Salmonella enterica; Salmonella enteritidis; Listeria monocytogene
      This is an update of a previous registration. [redacted] will be putting chlamydia into animals. He will be submitting an IACUC application. The Committee recommended the use of BSL2 practices, microisolator cages and autoclaving of the bedding and cages. On these conditions, the work was approved at BSL2.

2. **Recombinant DNA protocols**
   1. [redacted], **B03-0008-**Effect of homeobox gene expression on *in vivo* angiogenesis
      Analysis of Nkx3.1 function in prostate epithelial cells
      This work was initially approved in 1999. This new protocol has a slightly different delivery system. This work will be done in a biosafety cabinet and microisolator cages will be used. The protocol was re-approved by Mr. Finkernagel in conjunction with [redacted].
   2. [redacted], **B03-0009 Molecular Basis of Acute Promyelocytic Leukemia**
      The Committee felt that those working with lentivirus should have their blood tested every six months, mostly to allay fears rather than because the Committee felt it is necessary. A question was raised as to whether the NIH and the CDC require surveillance for lentivirus. Mr. Finkernagel will do a physical inspection of the [redacted] lab and practices. The Committee voted approval of this work at BSL2+ contingent on Mr. Finkernagel's recommendations and proper procedures and practices being used.

3. **Adjournment**
   The meeting was adjourned at 4:55 p.m.

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Institutional Biosafety Committee Meeting
Minutes
August 21, 2003

MEMBERS PRESENT: Joseph Bertino, Joseph Broderick, Scott Finkernagel, Patricia Sonsalla, Iris Udasin, Ellen Welch

1. **Approval of Minutes**
   The minutes of the May 15, 2003 meeting were approved unanimously.

2. **Recombinant DNA protocols**
   A. **B03-0007:** [redacted] **(Medicine)** Analysis of Nkx3.1 function in prostate epithelial cells
      This proposal uses Lentivirus to transfect human prostate epithelial cells to examine the consequences of expressing Nkx3.1 on prostate differentiation (see attached summary). Mr. Finkernagel summarized the proposal and the recommendation for BSL2+ practices. The committee encouraged that the blood of all those working with the vector be tested at the outset to establish a baseline. The committee voted unanimously to approve the protocol conditional on the acceptance of the recommendation for BSL2+ practices as outlined in the summary and standard practices (attached).
   B. **B03-0006** [redacted] **(Pharmacology)** Therapies for Lysosomal Storage Disease
      The study uses adeno-associated viral vectors for preclinical gene studies of lysosomal storage disorders using animal models. The vector is in Risk Group 1, meaning that the agent is not associated with disease in healthy adult humans. The bedding will be disinfected but does not require autoclaving and the animals sacrificed will be incinerated. Mr. Finkernagel recommended Approval Class B, with animal BL-1 conditions and the committee agreed unanimously.

3. **Pathogen Registries**
   The committee acknowledged receipt of the following pathogen registries:

   P03-0008 [redacted] **(Neurology)** Interferon-B Gene Therapy in an Animal Model of MS (summary attached).

4. **Select Agent Update**
   Mr. Finkernagel reported that during a laboratory inspection in the spring, a sample of Newcastle Disease Virus was found in [redacted] freezer. This virus, which is a High Consequence

Livestock Pathogen, had been brought from Roche with [redacted]. EOHSS is assisting in the process to send this sample to [redacted] Center for BioDefense facility in Newark.

5. **Odors in the MEB from autoclaving of animal bedding**
   The autoclaving of animal bedding in the vivarium in the [redacted] produces strong odors within the building. This issue has been a long-standing one and in the past several alternatives were investigated, but each of them created additional problems. The odor has been caused primarily because of the need to autoclave the bedding of [redacted] mice. [redacted] will soon (as early as this fall) move his mice into the vivarium in the [redacted] building. The committee felt that given the problems with the alternatives, the bedding should continue to be autoclaved at [redacted] and the situation will be re-evaluated after [redacted] moves his mice.

5. **Adjournment**
   The meeting was adjourned at 4:50 p.m.

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Office of Research and Sponsored Programs

Institutional Biosafety Committee Meeting
Minutes
May 15, 2003

MEMBERS PRESENT: Joseph Dougherty (chair), Joseph Bertino, Scott Finkernagel, Thomas Smith, Patricia Sonsalla, Iris Udasin, Ellen Welch

OTHERS PRESENT: Joseph Broderick

1. **Approval of Minutes**
   The minutes of the February 20, 2003 meeting were approved unanimously.

2. **Recombinant DNA protocols**
   A. Annual Review—[redacted] gene therapy trial: "A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ad5FGF-4 in Patients with Stable Angina"

   This protocol was reviewed in February 2002 and received IBC approval. At that time, the IBC requested a yearly update. This site of the study received IRB approval in July and began enrolling patients. Eight were enrolled, five have dropped out. (See attached memo from [redacted]) Regarding the adverse event at RWJUH, the question was raised as to whether the person suffering from unstable angina prior to receiving the study drug subsequently dropped out. Mr. Finkernagel will clarify with [redacted], the study coordinator. The committee also felt that we should have more current information on adverse events and serious adverse events, since the latest reports were from the fall of 2002. In general, the committee felt that it should receive timely reports on all serious adverse events in human gene therapy trials that our faculty are involved in whether they occur here or at any other site. Regarding this particular study, the committee felt that results were not significant, raising the question of the value of the study as a whole.

   B. Adverse event—[redacted] gene therapy trial: "Phase I Open Label Study to Evaluate Safety of PROSTVAC-VF-TRICOM in the Treatment of Subjects with Adenocarcinoma of the Prostate"

   A patient enrolled in this study was admitted to the hospital on March 21, 2003 with facial tingling and numbness on the right side (see attached report). The committee agreed with [redacted] assessment that the event was probably related to the progression of the disease than to the study drug.

3. **Pathogen Registries**
   None

4. **New Business**
   A. Update on new hazardous material survey

      Mr. Finkernagel presented an overview of a proposed new hazardous material survey for the entire Medical School. A Pathogen Registry was established for the Medical School in 1995. At present, 50 investigators have registered pathogens out of a total of 175 "responsible investigators" listed for the school. (A "responsible investigator" is one who has responsibility for research laboratory space.) We are now operating in a political environment that requires more stringent oversight over potential hazards in the labs. New regulations regarding select agents from CDC and USDA, the CDC's participation in the worldwide effort to eliminate wild poliovirus, and federal anti-terror legislation have combined to make it seem like a good idea to do a comprehensive survey of biohazards at the Medical School. Mr. Finkernagel is working with Mr. Broderick in the research office to design a survey to identify possession of select agents, wild poliovirus, or any agents requiring handling at BSL-2 or greater in the labs. The survey will be prepared this spring and summer.

   B. New Biosafety Plan

      A new laboratory safety plan is being prepared. Mr. Finkernagel passed out copies of the biosafety plan component for review.

5. **Adjournment**
   The meeting was adjourned at 5:15 p.m.