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# UAMS UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES www.uams.edu/safety

## Fax Cover Sheet

To:	The Sunshine Pro	oject	From:	Karen Beenken, Ph.D.
Company:			Department:	Occupational Health and Safety
Fax No.:	1-512-494-0545		Fax No.:	(501) 296-1339
Phone No.:			Phone No.:	
Re:	IBC minutes		Date:	April 28, 2006
Total Pages	Including Cover Sheet:	32	Time:	09:15 am

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### BIOSAFETY COMMITTEE MINUTES

May 2, 2003

#### 1. Protocol

Investigator: Dr. Xuming Zhang

Recombinant work using coronavirus SARS RNA.

This biosafety protocols was approved by the Biosafety Committee. Please amend your protocol to include room numbers in items 7a. Designated work areas; and 7b Storage.

### Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman

CornettMacLeodEisenachRobbinsHinsonSaylorsLynchSteadmanQuality AssuranceZhang

### BIOSAFETY COMMITTEE MINUTES

May 2, 2003

#### 1. Protocol

Investigator: Dr. Xuming Zhang

Coronavirus SARS.

This biosafety protocol was approved by the Biosafety Committee with the following amendments.

- 7. Add: The outer the outer door to the BSL3 should be marked with the agent name and the researchers name and emergency contact number.
- 7b. Add: in BSL-3.
- 7e. Add: Must use N95 masks, and all workers must have a medical screen and be fit tested before they can wear this mask. Contact OH&S to schedule.
- 7g. 2) Add: Need a detailed protocol for spill response for this agent. E.g. Immediately leave the room. Close all doors. Keep others out. Don PAPR with HEPA filters and return. Flood area with 10 % bleach solution. (Similar to a TB spill protocol. Talk with David Carroll about this.)
- 7h. Add: All waste must be <u>autoclaved</u> prior to being red bagged for disposal with biohazardous waste.
- 9. Add: Any accidental exposure must be reported immediately. The employee should be seen in Student and Employee Health (SEHS) for evaluation as soon as possible. Complete an Incident and Injury Report form and take it with you to SEHS.

NOTE: Additionally all researchers using the BSL-3 must be oriented to it's use and appropriate protocols...e.g. emergency alarms, emergency call box etc. prior to beginning work in the facility.

Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman

Cornett MacLeod
Eisenach Robbins
Hinson Saylors
Lynch Steadman
Quality Assurance Zhang

### UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES BIOSAFETY COMMITTEE MINUTES May 8, 2003

#### 1. Protocol

Investigator: Dr. Behjatolah M. Karbassi

Agents: N-nitroso-N-methylurea (MNU) and 7,12-dimethylbenz(a)anthracene (DMBA).

The Biosafety Committee reviewed this biosafety protocol, but it needs revision. Please amend and expand your protocol according to the following comments. The revised protocol will be reviewed as soon as it is received.

- a. Item 7b. Specify the stock quantities of the compounds to be stored.
- b. Item 7b. Specify the method(s) of securing the agents.
- c. Item 7f. Specify the types of respiratory cartridge(s) to be used.
- d. Item 7g. Change "unknown" to none, if appropriate.
- e. Item 7h. Decontamination should be with soap and water
- f. Item 7h. The description of procedures in the event of spills should be expanded, particularly for NMU.
- g. Item 7h. Change "mask" to respirator
- h. Item 7i. Specify the professional waste disposal service to be used.
- i. Item 8d6. Change "mask" to respirator.

Also address the following questions.

Should Laboratory Animal Medicine personnel wear a respirator?
Will animal carcasses and litter be incinerated by the designated professional waste disposal service?

It is important that you revise the biosafety protocol and consult with professionals in the Department of Laboratory Animal Medicine to arrange for animal isolation and special handling PRIOR to initiating experimentation.

### Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman MacLeod
Cornett Robbins
Eisenach Saylors
Hinson Steadman
Lynch Karbassi

Quality Assurance

Animal Care and Use Committee

### BIOSAFETY COMMITTEE MINUTES

### August 19, 2003

#### 1. Protocol

Investigator: Dr. Junming Zhang

Agent: Florocitric acid.

Reviewers requested clarification on several items and the form was revised. This biosafety protocols was approved by the Biosafety Committee.

### Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman

Cornett MacLeod
Eisenach Robbins
Hinson Saylors
Lynch Steadman
Quality Assurance Zhang

### BIOSAFETY COMMITTEE MINUTES

August 21, 2003

### 1. Protocol

Investigator: Dr. Tim Chambers

Paclitaxol.

This biosafety protocols was approved by the Biosafety Committee.

Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman

Cornett MacLeod
Eisenach Robbins
Hinson Saylors
Lynch Steadman
Quality Assurance Chambers

### BIOSAFETY COMMITTEE MINUTES

August 29, 2003

### 1. Protocol

Investigator: Dr. Lee S.F. Soderberg, Dr. Wayne L. Gray

Agent: Human immunodeficiency virus-1 (HIV-1).

This biosafety protocols was approved by the Biosafety Committee.

### Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman

Cornett MacLeod
Eisenach Robbins
Hinson Saylors
Lynch Steadman
Quality Assurance Gray
Animal Care and Use Committee

### BIOSAFETY COMMITTEE MINUTES

### September 17, 2003

#### 1. Protocol

Investigator: Dr. Charlotte Peterson

Cardiotoxin.

This biosafety protocols was approved by the Biosafety Committee with the following recommendations:

- 1. For emergency treatment of accidental exposure, the availability of antvenin should be determined.
- 2. Since death can rapidly result from envenomation, exposed individuals should be referred to the Emergency Room.
- 3. Venom should be stored locked in a controlled access area.

Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman

Cornett MacLeod
Eisenach Robbins
Hinson Saylors
Lynch Steadman
Quality Assurance Peterson

Animal Care and Use Committee

Office of Research and Sponsored Programs

### BIOSAFETY COMMITTEE MINUTES

### September 26, 2003

### 1. Protocol

Investigator: Dr. Yi-Hong Zhou

PAX6 gene delivery using Adenoviirus.vector

This biosafety protocols was approved by the Biosafety Committee:

### Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Coleman

Cornett MacLeod
Eisenach Robbins
Hinson Saylors
Lynch Steadman
Quality Assurance Zhou

Office of Research and Sponsored Programs

### BIOSAFETY COMMITTEE MINUTES

### November 13, 2003

1. Protocol: Diphtheria toxin.

Investigator: Dr. Robert S. Weinstein

This Biosafety Committee has reviewed the Biosafety protocol for the above referenced project and approved with the following recommendation:

For decontamination: Bleach, acidification, or other treatment should be used to denature the toxin.

### Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. M. Coleman V. MacLeod
Dr. L. Cornett Dr. V. Robbins
Dr. K. Eisenach Dr. R. Saylors
Dr. J. Hinson A. Steadman

Dr. T. Lynch Office of Research Administration
Quality Assurance Animal Care and Use Committee

Dr. R. Weinstein

### BIOSAFETY COMMITTEE MINUTES

March 3, 2004

1. Protocol: Herpes simplex virus thymidine kinase gene for transgenic mice.

Investigator: Dr. Robert L. Jilka

This Biosafety Committee has reviewed the biosafety protocol for the above referenced project. The BL-1 precautions described in the safety protocol are appropriate transgene procedures, however, Dr. Jilka did not specify the source of the HSV tk gene. The Committee asks that Dr. Jilka provide a revised biosafety protocol if HSV is used. If the HSV tk gene is generated in another laboratory, please identify the laboratory.

### Lee S.F. Soderberg, Ph.D., Chairman, Biosafety Committee

cc. Ms. M. Coleman Ms. V. MacLeod
Dr. L. Cornett Dr. V. Robbins
Dr. K. Eisenach Dr. R. Saylors
Dr. J. Hinson Dr. T. Hendrickson

Dr. T. Lynch Office of Research Administration
Quality Assurance Animal Care and Use Committee

Dr. R. Jilka



Minutes

March 9, 2004

The Biosafety Committee reviewed two protocols submitted by Dr. Randall Breau, Principal Investigator.

 A Phase III, Multi-Center, Open Label, Randomized Study to Compare the Overall Survival and Safety of Bi-weekly Intratumoral Administration of INGN 201 versus Weekly Methotrexate in 240 Patients with Refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN) [Study T-301]

This protocol was previously approved and has been amended to replace Dr. Hanna with Dr. Kokoska. Biosafety procedures have not been modified. The IBC approved this protocol.

2. A Phase III, Multi-Center, Open Label, Randomized Study to Compare the Effectiveness and Safety of Intratumoral Administration of INGN 201 in Combination with Chemotherapy versus Chemotherapy Alone in 288 Patients with Recurrent Squamous Cell Carcinoma of the Head and Neck (SCCHN) [T302]

This protocol was previously approved and has been amended to replace Dr. Hanna with Dr. Kokoska and change patient numbers. Biosafety procedures have not been modified. The IBC approved this protocol.

Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman

Dr. L. Cornett

Dr. K. Eisenach

Dr. J. Hinson

Dr. T. Lynch

Ms. V. MacLeod Dr. V. Robbins

Dr. R. Saylors Dr. T. Hendrickson

Office of Research Administration

Dr. R. Breau

IRB



**Minutes** 

March 24, 2004

The Biosafety Committee reviewed a protocol submitted by Dr. Zhiyong Zhao, Principal Investigator, for the use of defective adenovirus. This protocol was approved by the IBC.

Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman

Dr. L. Cornett Dr. K. Eisenach

Dr. J. Hinson

Dr. T. Lynch

Dr. Z. Zhao

Ms. V. MacLeod

Dr. V. Robbins

Dr. R. Saylors

Dr. T. Hendrickson

Office of Research Administration



Minutes

**April 30, 2004** 

The Biosafety Committee reviewed a protocol submitted by Zabeena Shaik for Dr. Grazyna Nowak, Principal Investigator, for the use of defective adenovirus. This protocol was revised and approved by the IBC.

Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

Ms. M. Coleman Ms. V. MacLeod CC. Dr. V. Robbins Dr. L. Cornett Dr. K. Eisenach Dr. R. Saylors

Dr. J. Hinson Dr. T. Hendrickson Dr. T. Lynch Office of Research Administration

Dr. G. Nowak Z. Shaik



#### **Minutes**

### May 11, 2004

The Biosafety Committee reviewed a protocol submitted by Dr. Marjorie Beggs for the use of a Lentivirus expression system. This protocol was approved by the IBC.

Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman Ms. V. MacLeod
Dr. L. Cornett Dr. V. Robbins
Dr. K. Eisenach Dr. R. Saylors
Dr. J. Hinson Dr. T. Hendrickson

Dr. T. Lynch Office of Research Administration

Dr. M. Beggs



#### **Minutes**

August 30, 2004

Committee members: L. Soderberg (Chair), M. Coleman, V. MacLeod, L. Cornett, V. Robbins, K. Eisenach, R. Saylors, J. Hinson, T. Hendrickson, T. Lynch

IBC meetings are regularly scheduled at 1:00 PM on the last Monday of each month in room B506E and are open to the public. Any corrections to these minutes should be sent to L. Soderberg.

- Based recommendations of the NIH Office of Biotechnology Activities (OBA), there will be a regularly scheduled time (1:00 PM on the last Monday of each month) for public comment of biosafety protocols under review. Member proxies will be accepted by e-mail or other means of communication.
- 2. The Biosafety Committee reviewed a protocol submitted by Dr. Chia Lee for the use of *Staphylococcus*. This protocol was approved by the IBC (For: Cornett, Eisenach, Hendrickson, Hinson, MacLeod, Robbins, Saylors, Soderberg; Comments by Hendrickson and MacLeod were addressed).
- 3. The Biosafety Committee reviewed a protocol submitted by Dr. Helen Benes for the use of mosquitoes. This protocol was approved by the IBC (For: Cornett, Hendrickson, MacLeod, Robbins, Saylors, Soderberg; Comments by Hendrickson were addressed).
- 4. The Biosafety Committee reviewed a protocol submitted by Dr. Kathleen Gilbert for the use of staphylococcal enterotoxin B. This protocol was approved by the IBC (For: Eisenach, Hendrickson, Hinson, MacLeod, Saylors, Soderberg; Comments by MacLeod were addressed).

### Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman Ms. V. MacLeod Dr. L. Cornett Dr. V. Robbins Dr. K. Eisenach Dr. R. Saylors Dr. J. Hinson Dr. T. Hendrickson

Dr. T. Lynch Office of Research Administration

Dr. K. Gilbert Dr. Chia Lee

Dr. Helen Benes



#### **Minutes**

September 27, 2004

Committee members: L. Soderberg (Chair), M. Coleman, V. MacLeod, L. Cornett, V. Robbins, K. Eisenach, R. Saylors, J. Hinson, T. Hendrickson, T. Lynch

IBC meetings are regularly scheduled at 1:00 PM on the last Monday of each month in room B506E and are open to the public. Any corrections to these minutes should be sent to L. Soderberg.

- 1. The Biosafety Committee reviewed a protocol submitted by Dr. Xuming Zhang for the use of influenza virus. This protocol was approved by the IBC (For: Cornett, Eisenach, Hendrickson, Hinson, MacLeod, Saylors, Soderberg; Comments by Hinson and Saylors were addressed).
- 2. The Biosafety Committee reviewed a protocol submitted by Dr. Mayumi Nakagawa for the use of vaccinia virus. This protocol was approved by the IBC with the recommendation that workers be vaccinated unless the strain is highly attenuated. (For: Cornett, Hendrickson, MacLeod, Robbins, Saylors, Soderberg; Comments by Robbins were addressed).
- 3. The Biosafety Committee reviewed a protocol submitted by Dr. Laura Hutchins for gene therapy with a gene for GM-CSF using an adenovirus vector. This protocol was approved by the IBC with the contingency that contaminated needles be disposed of properly. (For: Cornett, Eisenach, Hendrickson, MacLeod, Robbins, Saylors, Soderberg; Comments by Cornett, Hendrickson, and Robbins were addressed).

### Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman

Dr. L. Cornett

Dr. K. Eisenach

Dr. J. Hinson

Dr. T. Lynch

Dr. X. Zhang

Dr. M. Nakagawa

Dr. L. Hutchins

Ms. V. MacLeod

Dr. V. Robbins

Dr. R. Saylors

Dr. T. Hendrickson

Office of Research Administration



#### **Minutes**

February 28, 2005

Committee members: L. Soderberg, M. Coleman, V. MacLeod, L. Cornett, V. Robbins, K. Eisenach, R. Saylors, J. Hinson, T. Hendrickson, T. Lynch

IBC meetings are regularly scheduled on the last Monday of each month and are open to the public. A special meeting will be held on March 16 at 9:00 AM in room B500. Any corrections to these minutes should be sent to L. Soderberg.

1. The Biosafety Committee reviewed a protocol submitted by Dr. Charles O'Brien for the generation of mice transgenic with RANKL promoter-luciferase constructs and mice with a deletion of a putative enhancer. This protocol was approved by the IBC.

- 2. The Biosafety Committee reviewed a protocol submitted by Dr. Manoj Agarwal entitled, UARK 2004-44 A phase III randomized, open-label study of CG1940 and CG8711 versus docetaxel and prednisone in patients with metastatic hormone-refractory prostate cancer who are chemotherapynaïve (Cell Genesys Protocol G-0029). This protocol was approved by the IBC. A suggestion was made to generate a specialized gene therapy protocol form to be completed by the Principal Investigator. This will be discussed at our March meeting.
- 3. Approval was given to Dr. Stavroula Kousteni for rDNA studies that comply with NIH/CDC guidelines and do not require IBC review.

### Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman Ms. V. MacLeod
Dr. L. Cornett Dr. V. Robbins
Dr. K. Eisenach Dr. R. Saylors
Dr. J. Hinson Dr. T. Hendrickson

Dr. T. Lynch Office of Research Administration

IACUC IRB (Jennifer Sharp)

Drs. O'Brien, Agarwal, Kousteni



#### **Minutes**

March 16, 2005

Committee members present: L. Soderberg, V. Robbins, K. Eisenach Committee members absent: M. Coleman, V. MacLeod, L. Cornett, R. Saylors, J. Hinson, T. Hendrickson, T. Lynch

- 1. Based on NIH OBA requirements, the Biosafety Committee must convene face-to-face meetings at which protocols are discussed. E-mail cannot substitute for this.
- 2. The meeting was cancelled due to lack of a quorum.

Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman Ms. V. MacLeod
Dr. L. Cornett Dr. V. Robbins
Dr. K. Eisenach Dr. R. Saylors
Dr. J. Hinson Dr. T. Hendrickson
Dr. T. Lynch



#### **Minutes**

April 8, 2005

Committee members present: M. Coleman, V. MacLeod, J. Hinson, V.

Robbins, R. Saylors, L. Soderberg

Committee members absent: L. Cornett, T. Hendrickson, T. Lynch, , K.

Eisenach

1. Based on NIH OBA requirements, the Biosafety Committee must convene face-to-face meetings at which protocols are discussed. E-mail cannot substitute for this. We will try to identify a regular, monthly time when all members could theoretically be present, possibly for lunch. Meetings would be on an as-needed basis.

 Biosafety protocols must be periodically reviewed. Some institutions have annual reviews, while others review every 3 or 5 years. This could be as simple as sending investigators a memo asking if procedures/conditions had changed. A motion to institute annual reviews was made (Coleman),

seconded (MacLeod), and passed (unanimous).

Dr. David Carroll submitted a protocol for work on Burkholderia pseudomallei. This organism produces an acute lung infection on aerosol exposure and is listed as a "select agent" based on its potential as a bioweapon. The NIH recommends BL-2 precautions or BL-3 if there is a high potential for aerosol or droplet production or production quantities or concentrations are generated. Dr. Carroll's work will be in the BL-3 facility. B. pseudomallei contains the genes necessary to synthesize the stress-protective sugar, trehalose. In other organisms, disruption of trehalose synthesis interferes with virulence and could suggest new antimicrobial therapies. Two genes, otsA and otsB, that regulate trehalose synthesis will be mutated and transfected into B. pseudomallei. If anything transfection of these genes should reduce virulence. However, selection of transfected organisms will be by introducing a chloramphenicol-resistance gene. NIH guidelines state that introduction of antibiotic resistance to pathogens must be approved by RAC unless resistance to that antibiotic occurs naturally. In fact, about 7% of B. pseudomallei strains are resistant to chloramphenicol (J. Antimicrobial Chemotherapy 24:295-309, 1989). The bottom line is: if this modified organism entered the community, would treatment be compromised? Routine treatment is with a cocktail of antibiotics and chloramphenical resistance should not pose a problem to treatment effectiveness. A motion

to approve these protocols was made (Coleman), seconded (MacLeod), and passed (unanimous).

4. Transgenic core. We approved the core to produce transgenic mice with the stipulation that investigators would notify the IBC in writing of the identity of genes to be transferred or deleted before the work is started. Dr. Charles O'Brien will be contacted to remind him of this requirement.

Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. Ms. M. Coleman
Dr. L. Cornett
Dr. K. Eisenach
Dr. J. Hinson
Dr. T. Lynch
Dr. D. Carroll

Ms. V. MacLeod
Dr. V. Robbins
Dr. V. Robbins
Dr. R. Saylors
Dr. T. Hendrickson
Dr. K. Beenken



**Minutes** 

May 20, 2005

Committee members present: L. Soderberg, K. Beenken, M. Coleman, L. Cornett, J. Hinson, V. MacLeod, V. Robbins, R. Saylors

Committee members absent: K. Eisenach, T. Hendrickson, T. Lynch

- 1. Dr. Karen Beenken was introduced as the new UAMS Biological Safety Officer. Steps will be taken to officially appoint her to this committee.
- 2. There was a general discussion about the interactions between the UAMS IBC and the VA and ACH. The UAMS IBC is registered with the OBA and has representatives from the VA (Eisenach) and ACH (Saylors). Neither the VA nor the ACH presently has an IBC that is registered with the OBA. The UAMS IBC will review protocols by UAMS faculty at the VA and at ACH on request. Dr. Peterson's protocol is for work at the VA, part of which is at UAMS. The protocol submitted by Drs. Simmen and Badger is for work at the ACH. The VA requires that research there be reviewed by a VA IBC and that committee may soon register with the OBA. The committee discussed making formal arrangements with ACH, including possibly adding the ACH Safety Officer as a member of our committee. Dr. Soderberg will contact Dr. Jacobs in this regard.
- 3. The protocol for the use of azoxymethane submitted by Drs. Simmen and Badger was presented by Dr. Jack Hinson. The protocol is to determine dietary factors that alter intestinal tumors produced by azoxymethane in Sprague Dawley rats. Azoxymethane is a volatile carcinogen and a mutagen that produces tumors in the intestines. Its low boiling point coupled with its carcinogenicity makes it an extremely hazardous chemical and procedures to decrease risk of human exposure should be followed rigorously.

The material safety data sheet indicates that for safe handling utilization of a disposable laboratory suit, safety glasses, two pairs of protective gloves, and NIOSH/MSHA approved respirator with mechanical exhaust be used. The protocol indicates that two pairs of gloves, coveralls, safety glasses,

and mask. The investigators should specify what type of gloves, coveralls, and mask will be utilized. Because of the volatility of the chemical, the NIOSH approved respirator should be used. A 1/2 face respirator with organic vapor cartridges is recommended by the UAMS Industrial Hygiene Officer. Workers should be fit-tested for respirator use. Also, the investigators should specify what type of solvent is utilized to dissolve the carcinogen and if the solvent can penetrate the gloves. A number of solvents can penetrate latex gloves and thus latex gloves may not be acceptable.

The material safety data sheet indicates that spills should be initially cleaned with a towel soaked in a suitable combustible solvent and this is to be followed by soap and water. In the protocol it is stated that spills are wiped up with paper towels and absorbent pads with plastic backing followed cleaning with soap and water. Decontamination of animal rooms should not be by sweeping as indicated in the protocol. The procedure should follow that stated in the material safety data sheet. A motion was made and passed unanimously that the investigators revise

their protocol according to the above comments for resubmission.

4. Dr. Peterson's protocol was presented by Dr. Soderberg. Dr. Peterson is studying muscle regenerating stem cells and their regulation by Wnt signaling. The model is to damage mouse muscles with a cardiotoxin (snake venom) and inject muscle stem cells with or without rDNA constructs. Disposable gloves, face mask, lab coat or scrub suit, and goggles of face shield will be used. Waste will be put in biohazard waste containers. Extremely low doses used for injection should pose few problems, but upon accidental exposure, personnel will report to Student-Employee Health.

Both AAV and the lentivirus system, which will be used as vectors, are replication defective. However, they can transfer genes to human cells and, thus, BL-2 precautions will be used. Work will be in the Aging Center (3131) with key card access and will be done in a biosafety cabinet. Workers will wear gloves, face mask, lab coat, and goggles. Genes to be transferred are BL-1 metabolic genes related to the Wnt

signaling pathway. Transfected animals will not be maintained longer than 12 days.

The IBC had no concern with this protocol. The IBC unanimously approved this protocol.

Source: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org

cc. Dr. Karen Beenken
Dr. L. Cornett
Dr. T. Hendrickson
Dr. T. Lynch
Dr. V. Robbins
Dr. F. Simmen

Ms. M. Coleman
Dr. K. Eisenach
Dr. J. Hinson
Ms. V. MacLeod
Dr. R. Saylors
Dr. T. Badger

Dr. C. Peterson



**Minutes** 

September 23, 2005

Committee members present: L. Soderberg, K. Beenken, M. Coleman, L. Cornett, J. Hinson, K. Eisenach, V. MacLeod, R. Saylors

Committee members absent: T. Hendrickson, T. Lynch, V. Robbins

- 1. Dr. Jason Chang's protocol for the use of methylmercury was discussed. Methylmercury is very dangerous and should be used with utmost caution. This protocol raised many questions among the IBC, such as whether the methylmercury was mono- or di-methyl, what the diluent/solvent would be, and what the total amount would be. The protocol cited the use of biosafety cabinets, but there was concern about contamination of the HEPA filters and it was suggested that a fume hood would be more appropriate for dissolving the powder, while a laminar flow hood could be used for later steps. However, the fume hood to be used must be tested. Protective apparel should include two layers of gloves (laminate and chemical gloves), a respirator, and foot covers. Spills should be dealt with using a wet mop, rather than sweeping, and disposal should not be down the drain. It was suggested that NCTR might have better facilities for safely using this compound. The IBC unanimously decided to ask Dr. Chang to revise his protocol according to MSDS and IBC recommendations and possibly meet with the Committee.
- 2. Dr. Yevgeniy Apostolov submitted a protocol to study cigarette smoke condensate. The CSC is generated at the University of Kentucky as a solution in DMSO. The DMSO is to be evaporated leaving a water-soluble extract. Because DMSO quickly permeates the skin with anything dissolved in it, the IBC was concerned about handling procedures while in DMSO solution. Regular gloves, as proposed (item #7f), are not adequate to protect investigators from the DMSO solution and chemical gloves may be necessary. Routine decontamination (item #7h1) should be done with a detergent. The IBC requested that the protocol be revised accordingly.

- 3. Dr. Kathy Eisenach submitted a protocol for the generation of kanamycinand streptomycin-resistant strains of *Mycobacterium tuberculosis*. Dr. Eisenach was present to discuss this protocol, but was excluded from the vote. Antibiotic-resistant M. tuberculosis occur naturally, therefore RAC review is not indicated. These mono-resistant strains would be used in tissue culture. All work will be in the VA BSL-3 facility, which has redundant security and has been certified. This protocol was approved.
- 4. Dr. Beenken proposed sending a survey to all UAMS investigators regarding the use of all infectious agents and rDNA work. This will provide better and current information about this type of work on campus. A draft of the form was circulated for review.

### Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc.	Dr. Karen Beenken	Ms. M. Coleman
	Dr. L. Cornett	Dr. K. Eisenach
	Dr. T. Hendrickson	Dr. J. Hinson
	Dr. T. Lynch	Ms. V. MacLeod
	Dr. V. Robbins	Dr. R. Saylors
	Dr. J. Chang	Dr. Y. Apostolov
	Dr. C. Peterson	



**Minutes** 

1

November 28, 2005

Committee members present: L. Soderberg, K. Beenken, M. Coleman, L. Cornett, J. Hinson, K. Eisenach, V. MacLeod, V. Robbins, T. Hendrickson (proxy)

Committee members absent: T. Lynch, R. Saylors,

- Dr. Jason Chang's protocol for the use of monomethylmercury was
  discussed. Dr. Chang provided satisfactory responses to IBC comments
  from our September meeting. Several issues were discussed.
  Occupational Health and Safety (OH&S) will check the fume hood to be
  used. Media and plasticware exposed to the monomethylmercury may
  need to be disposed through OH&S and may involve a charge (contact Lou
  Kiene). The protocol should be corrected in places citing "EH&S" to
  OH&S. The IBC unanimously approved the protocol pending receipt of a
  revised version of the protocol.
- 2. Dr. Frank Simmen (ACH) submitted a protocol for rDNA using rAAV-8 as a vector. The protocol was approved. IBC vote was unanimous.
- 3. Dr. Kathryn Thrailkill and Dr. Charles Lumpkin (ACH) submitted a protocol for rDNA using a defective adenovirus as a vector. The protocol was unanimously approved. A question arose as to whether streptozocin used in the protocol should be reviewed as a carcinogenic compound. The ACH has a site-specific biosafety review process, which should be sufficient. If the investigators or Richard James, the ACH Safety Officer, would like us to review it, we would be happy to.
- 4. Dr. Brendan Stack and Dr, Brett Clarke submitted a protocol for the use of fusaric acid and paclitaxel. The IBC had concern about this protocol. The investigator should consult the UAMS Administrative Guide (11.4.15) for proper handling of chemotherapeutic drugs. The investigators should contact OH&S for guidance. The biosafety protocol should completed, not just references to the MSDS. A respirator, rather than a surgical mask,

should be used and the investigators should be fit-tested. The responsible investigators should complete the UAMS Chemical Hygiene course. This protocol was not approved as submitted. The IBC requested that the protocol be revised and re-submitted.

- 5. Dr. Robert Weinstein submitted a protocol for the use of diphtheria toxin. The IBC made the following recommendations: 1) that personnel be up-to-date on DT vaccination, 2) that a respirator (with fit-testing) be used during handling of the powder, 3) that puncture-resistant or double gloves be used during injections, 4) that the investigators complete the UAMS Chemical Hygiene course. The IBC unanimously approved the protocol pending receipt of a revised version of the protocol.
- 6. Dr. Beenken proposed sending a survey to all UAMS investigators regarding the use of all infectious agents and rDNA work. This will provide better and current information about this type of work on campus. The IBC made several suggestions, including calling it a required audit, not asking for lists of stockpiled agents, and making it part of the annual lab audits on the UAMS campus.
- 7. The Committee discussed setting a regular meeting time so that members can plan ahead. Noon on the third Friday of each month in which we have business was suggested.

### Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc.	Dr. Karen Beenken	Ms. M. Coleman
	Dr. L. Cornett	Dr. K. Eisenach
	Dr. T. Hendrickson	Dr. J. Hinson
	Dr. T. Lynch	Ms. V. MacLeod
	Dr. V. Robbins	Dr. R. Saylors
	Dr. J. Chang	Dr. F. Simmen
	Dr. K. Thrailkill	Dr. C. Lumpkin
	Dr. B. Stack	Dr, B. Clarke
	Dr. R. Weinstein	Mr. R. James



**Minutes** 

January 20, 2006

Committee members present: L. Soderberg, K. Beenken, M. Coleman, A. Estes, T. Hendrickson, J. Hinson, V. MacLeod, V. Robbins,

Committee members absent: R. Saylors, L. Cornett, K. Eisenach,

- 1. Dr. Michael Borrelli's protocol for rDNA studies using an adenovirus to deliver cytolethal distending toxin B genes to tumor cells was discussed. The IBC unanimously approved the protocol with two changes. 1) Item 8d, which states that needles will be placed into a containment bag, should instead indicate that needles will be placed in a sharps container. 2) Item 8h should be modified to state that the paper lining of rabbit cages will be placed in a biohazard bag for autoclaving, since autoclaving the large rabbit cages is impractical. Dr. Robbins has discussed the latter issue with Dr. Borrelli.
- 2. The Committee discussed annual review of biosafety protocols. Last summer we decided to up-date all protocols annually. It was suggested that the best format for up-date was to integrate it with the annual lab audits. Principal investigators will be asked if they would like to renew the protocol and if there are any changes to it. Substantial changes will require that a new protocol be submitted to the IBC. The IBC will be presented with a list of renewals, if any, at each meeting and will vote on renewal.

### Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. K. Beenken
L. Cornett
A. Estes
J. Hinson
V. Robbins
Ms. M. Coleman
Dr. K. Eisenach
Dr. T. Hendrickson
V. MacLeod
Dr. R. Saylors
M. Borrelli



#### **Minutes**

February 17, 2006

Committee members present: L. Soderberg, K. Beenken, L. Cornett, A. Estes, J. Hinson, V. MacLeod

Committee members absent: M. Coleman, K. Eisenach, T. Hendrickson, V. Robbins, R. Saylors

- Dr. Larry Johnson submitted two protocols for rDNA studies using murine leukemia virus derived retrovirus and equine infectious anemia virus vectors. The IBC unanimously approved these protocols with the recommendation that the biosafety cabinets be up to date in their certification and that lab personnel take the chemical hygiene course, if they haven't already done so.
- 2. Dr. Kevin Raney submitted a protocol for rDNA studies transferring hepatitis C virus genes into E. coli BL21 and the noninfectious HCV replicon into Huh-1 liver cells. The IBC unanimously approved this protocol with the recommendation that, for disposal, the bleach solution used should be 5-10% and that petri dishes be placed in orange biohazard bags for autoclaving and disposal.
- Dr. Manoj Agarwal submitted a revised protocol for human gene therapy (UARK 2004-44). This protocol was originally approved by the IBC on February 28, 2005. The revisions do not affect biosafety procedures. The IBC approved this protocol.
- 4. Annual review: Dr. Grazyna Nowak's biosafety protocol using a defective adenovirus vector had no changes and was approved.
- 5. The Committee previously decided that annual review of biosafety protocols should be done in conjunction with annual lab audits. Since lab audits do not cover clinical studies, a separate scheduling will have to be established to complete annual reviews of gene therapy protocols.

Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. K. Beenken M. Coleman
L. Cornett K. Eisenach
A. Estes T. Hendrickson
J. Hinson V. MacLeod
V. Robbins R. Saylors
K. Raney L. Johnson
M. Agarwal A. Cato



**Minutes** 

March 17, 2006

Committee members present: L. Soderberg, K. Beenken, L. Cornett, A. Estes, J. Hinson, V. MacLeod, V. Robbins

Committee members absent: K. Eisenach, T. Hendrickson, R. Saylors

- 1. Mary Ann Coleman has taken a new position as Associate Hospital Administrator and has resigned from the IBC. Mary Ann has given many years of service to the Committee and her expertise has been a much appreciated contribution to the IBC. Dr. Karen Beenken, Biosafety Officer, has already been appointed to the IBC and will replace Ms. Coleman.
- 2. Dr. Roger Rank submitted a protocol for *Neisseria gonorrhoeae*, to be used in a guinea pig model of genital infection. The IBC unanimously approved this protocol.
- 3. Dr. Nalini Bora submitted a protocol for the use of complete Freund's adjuvant and pertussis toxin in a rat model. The IBC unanimously approved this protocol with the recommendation that chemical resistant gloves be used in handling pertussis toxin and that, in case of a major spill (item 7h2), Occupational Health and Safety be contacted, not Dr. Soderberg.
- 4. Dr. Mark Crew submitted a protocol rDNA transferring gene from porcine cytomegalovirus (PCMV), a BSL-2 organism. PCMV is not infectious for humans and it is highly unlikely that the genes will pose a problem. The IBC unanimously approved this protocol.

### Lee S.F. Soderberg, Ph.D. Chairman, Biosafety Committee

cc. K. Beenken
L. Cornett
A. Estes
J. Hinson
V. Robbins
R. Rank
M. Coleman
K. Eisenach
T. Hendrickson
V. MacLeod
R. Saylors
N. Bora
M. Crew