



COMITE DE BIOSEGURIDAD
BIOSAFETY COMMITTEE

UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MEDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR
OFFICE OF THE CHANCELLOR

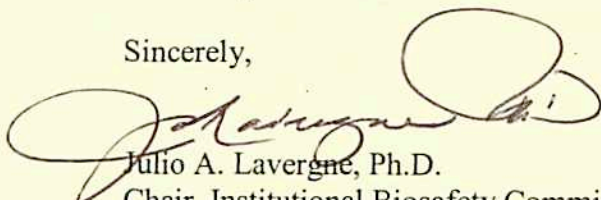
May 5, 2006

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

Dear Mr. Hammond:

As per your request of letter of 15 March, 2006, please find enclosed the minutes (May 1, 2003-present) of the Institutional Biosafety Committee of the Medical Sciences Campus, University of Puerto Rico.

Sincerely,



Julio A. Laverne, Ph.D.
Chair, Institutional Biosafety Committee
Medical Sciences Campus
University of Puerto Rico

Vo/Bo:



Mr. Irving Jimenez, Dean of Administration

c/Luis Torres Bauza, Ph.D., Special Assistant to the Chancellor

**UNIVERSITY OF PUERTO RICO
MEDICAL SCIENCES CAMPUS
INSTITUTIONAL BIOSAFETY COMMITTEE**

**To: Edgard H. Hammond
Director
The Sunshine Project**

**From: Julio Lavergne, Ph. D.
Chair, Institucional Biosafety Committee**

Date: May 12, 2006

Subject: Minutes of the IBC.

Comments:

**Enclosed you will find copies of the minutes from 2003 until the present year.
If you have any questions or need further clarification, don't hesitate to call
us at 787-758-2525 ext. 2098 or at 787-758-2525, ext. 1647.**

BIOSAFETY COMMITTEE**Chairperson:** Loyda Meléndez, Ph.D**Date:** August 28, 2003**Next Meeting:** September 25**Location:** John B. Grant-4th floor**Time:** 11:00 AM

Members	Members Present	Members Excused	Guest
Joseph Bloom, Ph.D Carmen Cadilla, Ph.D Eddie González, MD Nancy Ildfonso, M.S. Melween Martínez, DVM Loyda Meléndez, Ph.D David Rhoe, RSO Iraida Robledo, Ph.D José A. Robles, MPH Carlos Rodríguez, Ph.D José R. Rodríguez, Ph.D	Carmen Cadilla, Ph.D Melween Martínez, Ph.D Loyda Meléndez, Ph.D David Rhoe, RSO Iraida Robledo, Ph.D José E. Robles, MPH Carlos Rodríguez, Ph.D José R. Rodríguez, Ph.D Vanessa Rodríguez, MPH	Joseph Bloom, Ph.D Eddie González, MD	Ivonne Jordán Margarita Reyes

TOPIC	DISCUSSION/CONCLUSION	ACTION/RECOMMENDATION	RESPONSIBILITY
Approval of Minutes	NA	NA	Biosafety Committee
Old Business	None		
New Business			
Carmen Zorilla, MD Study #1350103	The Committee is not authorized to approve this protocol based on NIH guidelines.	Recruit two people from the community to fulfill NIH guidelines.	Dr. Meléndez, Mr. Minsal and Mr. Rhoe
	In addition she needs to complete Section A and D of the application.	Waiting to receive sections A & D	Dr. Meléndez
Carmen Zorilla, MD Study #1350202, 1350102, and 1350302	NA	Approve as stated Recommendations: Suggestions to disinfect tubes before disposal. Blood Spill – Maintenance personnel should take training and sign a document indicating they attended the training.	Dr. Meléndez

Movies in the Compliance office
should be considered for training
personnel.

Idali Martínez, Ph.D
Study #246014

The Committee is not authorized
to approve this protocol based on
NIH guidelines.

Waiting to receive information.

Dr. Meléndez

Section A and E is incomplete and
must submit SOP for the animal
center.

Carlos A. Sariol, Ph.D
Study #8130203

Must fill out the new Biosafety
form.

Waiting to receive information

Dr. Meléndez

Must apply for a radioisotope
license or receive a letter from Dr.
Edmundo authorizing permission
to work under his license.

Provide SOP for animal disposal-
obtain from Dr. Melween Martínez

Provide hazards for Influenza and
safety measures for the employees

Recombinant DNA is not- exempt
List host/vector system for small
rDNA

List chemical and biological
agents-no abbreviations- involved
In the methods with appropriate
storage management and disposal

Name the personnel and state
training experience

NA

Approved as stated

Dr. Meléndez

Study # 324010 & 3240104

Recommendations:

- Use of hood for toxic chemical– no mask,
- Use a non-glass “brown glass bottles” for storage
- Combustible solvent – Fire hazard an explosive hazard.
- Use of a 15 gallon for collection – not a 55 gallon
- List which chemicals are going to be used with hood and with respiratory protection.
- How is the waste going to be disposed?

Approved as stated

Melween Martínez, DVM
Study # 6260202
Continuation

Pending for the Committee:

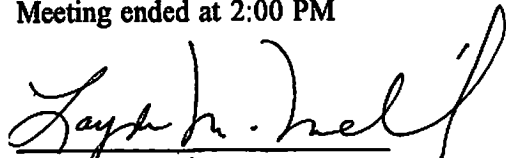
- Another meeting should be held to approve the two community members.
- Consider inviting the PI's to the Primary Evaluations.
- A new Biosafety Manual has been prepared by David Rowe and Vanesa Rodríguez for the Committee review. The Committee Chair will review it and thereafter will e-mail it to the members.

Committee Member's Suggestions:

- A Primary and secondary review for the projects should be held.
- Committee Members should obtain a copy of the studies, two weeks prior to the reviews, for evaluation.
- If the proposal is not approved, the reviewers should keep a copy of primary review as reference for the second review. The secretary must bring the files of the PI that have proposals to review for references to the reviewers.

- Write a letter to the Principal Investigator- Dr. Zorrilla, stating recommendations regarding Section A – D. We also need a description of the vector system. We want to know if the virus replicates. We have to provide to the NIH information if this construct has been used in humans before. The investigator will provide information, in the meantime, the Committee will recruit two (2) community members.
- A check-list form should be available for the primary and secondary reviewers, to make each opinion and recommendations valid.
- Reviewers must bring their written notes to each meeting and give them to the secretary.
- Modify the new form to ask if the SOP is on file, if yes, indicate to please include copy for committee to review, if the answer is no, your SOP should be submitted.

Meeting ended at 2:00 PM


Loyda M. Meléndez, Ph.D
Professor and Chairperson
Biosafety Committee

Approved by IBC on 8-28-03

BIOSAFETY COMMITTEE**Chairperson:** Loyda Meléndez, Ph.D**Date:** September 26, 2003**Next Meeting:** October 30**Location:** John B. Grant-4th floor**Time:** 11:00 AM

Members	Members Present	Members Excused	Guest
Joseph Bloom, Ph.D Carmen Cadilla, Ph.D Melween Martínez, DVM Loyda Meléndez, Ph.D Iraida Robledo, Ph.D José A. Robles, MPH Carlos Rodríguez, Ph.D José R. Rodríguez, Ph.D Vanessa Jiménez, RN Milena Arguello, BS	Joseph Bloom, Ph.D Carmen Cadilla, Ph.D Melween Martínez, DVM Loyda Meléndez, Ph.D Iraida Robledo, Ph.D José E. Robles, MPH Carlos Rodríguez, Ph.D José R. Rodríguez, Ph.D Vanessa Jiménez, RN	Milena Arguello, BS	Ivonne Jordán Margarita Reyes Idalí Martínez, Ph.D

TOPIC	CONCLUSION (August)	ACTION/RECOMMENDATION	RESPONSIBILITY
Approval of Minutes		If anyone, not including Committee Members, solicits a copy of the minutes the Committee Member's names should be omitted.	Biosafety Committee Secretary
Studies pending approval: Carmen Zorilla, MD Study #1350103	The Committee was not authorized to approve this protocol based on NIH guidelines. In addition she needs to complete Section A and D of the application.	Recruit two people from the community to fulfill NIH guidelines. Waiting to receive sections A & D	Dr. Meléndez, Mr. Minsal and Mr. Rhoe Dr. Meléndez
Idalí Martínez, Ph.D Study #246014	The Committee is not authorized to approve this protocol based on NIH guidelines. Section A and E is incomplete and must submit SOP for the animal center.	Waiting to receive information requested by Committee.	Dr. Meléndez

TOPIC	CONCLUSION (August)	ACTION/RECOMMENDATION	RESPONSIBILITY
María Sosa, Ph.D. Study # 324010 & 3240104	Which chemicals will be used with the hoods and which chemicals will be used with the mask?	Pre-approved until request information is submitted to Committee.	Dr. Meléndez
Carlos A. Sariol, Ph.D Study #8130203	Must fill out the new Biosafety form. Must apply for a radioisotope license or receive a letter from Dr. Edmundo authorizing permission to work under his license. Provide SOP for animal disposal-obtain from Dr. Melween Martínez Provide hazards for influenza and safety measures for the employees Recombinant DNA is not- exempt List host/vector system for small rDNA List chemical and biological agents-no abbreviations-involved in the methods with appropriate storage management and disposal Name the personnel and state training experience.	Waiting to receive information requested by Committee.	Dr. Meléndez
TOPIC	DISCUSSION (September)	ACTION	RESPONSIBILITY
Follow up: Carmen Zorilla, MD Study #1350103	Submitted documents required by committee.	Approved, but must send the Committee copies of the documents send to NIH	Dr. Meléndez
Idali Martínez, Ph.D Study #246014	Submitted documents required by committee.	Approved as stated	Dr. Meléndez
Carlos A. Sariol, Ph.D Study #8130203	Submitted documents required by committee.	Approved as stated	Dr. Meléndez
TOPIC	DISCUSSION(September)	ACTION	RESPONSIBILITY
New Studies: Nidza Lugo	<ul style="list-style-type: none"> Proposal was not included 	Not approved, until	Dr. Meléndez

Study #2710199	<ul style="list-style-type: none"> • No Biosafety Training • No Storage location specified • NPY an GABA expression in the aging ground squirrel system. • Clarify who is the licensed professional waste disposal service for chemical #1 • Chemical #10: Clarify disposition. • Clarify Location – Ex. REVCO, freezer in what room. • 5 and 10 are repeated in Section B • Did not Include Risk Communication – mandatory – OSHA 29 CFR 1910.1200 (HAZCOM) • Biomedical Disposal method mandatory – OSHA 29 CFR 1910.120 (HAZWORPR) • 	documents required by Committee are submitted.	
Mark W. Miller Study #2710299	<ul style="list-style-type: none"> • Lack of Chemical information • The following was not included: <ul style="list-style-type: none"> ◦ SOP's ◦ Biosafety Certificates ◦ Proposal • No Specific storage location • Disposition is not clear • Disposal method mandatory – OSHA 29 CFR 1910.120 (HAZWORPR) • Did not include Risk Communication – mandatory – OSHA 29 CFR 1910.1200 (HAZCOM) • What personal protection will be used for personel. • No personnel training included 	<ul style="list-style-type: none"> • Submit information on disposal methods, clarify 	Dr. Meléndez

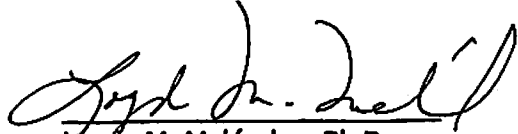
Pending for the Committee:

Revision of the Biosafety Manual. Amendments to the Biosafety form to include if SOP were available on file.

Committee Members Suggestions:

- Follow-Ups should be posted and sent to the Committee Members by the Committee's Secretary. (Example: A table indicating which documents have been submitted the Committee from the PI's)
- Chairperson should not approve a study until all documentation are submitted. (Example of letter written to PI – "Not approved until you submit required information.")
- The Chairperson will call the College of Chemistry to explore the possibility of offering continued education courses on Campus.

Meeting ended at 1:30 PM

A handwritten signature in black ink, appearing to read "Loyda M. Meléndez".

Loyda M. Meléndez, Ph.D
Professor and Chairperson
Biosafety Committee

Minutes taken By: Margarita Reyes Rivera

Approved by IBC on 9-26-03

BIOSAFETY COMMITTEE

Chairperson: Loyda Meléndez, Ph.D

Date: March 25, 2004

Next Meeting: April 22, 2004

Location: BioMedical Bldg. I

Time: 11:00 AM

Members

Bloom Oquendo, Joseph Ph.D
 Cadilla Vázquez, Carmen Ph.D
 Martínez Rodríguez, Melween DVM
 Meléndez Aponte, Loyda Ph.D
 Robledo Burgos, Iralda E., Ph.D
 Robles Pereira, José A. MPH
 Rodríguez Orengo, José F. Ph.D
 Rodríguez Sierra, Carlos J. Ph.D
 Jiménez Fossé, Vanessa MPH

Members Present

Cadilla Vázquez, Carmen Ph.D
 Martínez Rodríguez, Melween DVM
 Meléndez Aponte, Loyda Ph.D
 Robledo Burgos, Iralda E., Ph.D
 Robles Pereira, José A. MPH
 Rodríguez Orengo, José F. Ph.D
 Rodríguez Sierra, Carlos J. Ph.D

Members Excused

Bloom Oquendo, Joseph Ph.D
 Jiménez Fossé, Vanessa MPH

Guest

Margarita Reyes Rivera

TOPIC	DISCUSSION/CONCLUSION	ACTION/RECOMMENDATION	RESPONSIBILITY
Approval of Minutes			BioSafety Committee
Follow-up Nidza Lugo Study #2710199	NOT APPROVED: <ul style="list-style-type: none"> Proposal was not included No BioSafety Training No Storage location specified NPY an GABA expression in the aging ground squirrel system. Clarify who is the licensed professional waste disposal service for chemical #1 Chemical #10: Clarify disposition. Clarify Location – Ex. REVCO, freezer in what room. 5 and 10 are repeated in Section B Did not Include Risk Communication – mandatory – OSHA 29 CFR 1910.1200 (HAZCOM) Biomedical Disposal method mandatory – OSHA 29 CFR 1910.120 (HAZWORPR) 	<ul style="list-style-type: none"> Not approved, until documents required by Committee are submitted. Mailed a follow-up letter 	Loyda Meléndez, Ph.D

TOPIC	DISCUSSION/CONCLUSION	ACTION/RECOMMENDATION	RESPONSIBILITY
Mark W. Miller Study #2710299	NOT APPROVED: <ul style="list-style-type: none"> • Lack of Chemical information • The following was not included: <ul style="list-style-type: none"> ◦ SOP's ◦ BioSafety Certificates ◦ Proposal • No Specific storage location • Disposition is not clear • Disposal method mandatory – OSHA 29 CFR 1910.120 (HAZWORPR) • Did not Include Risk Communication – mandatory – OSHA 29 CFR 1910.1200 (HAZCOM) • What personal protection will be used for personnel? • No personnel training included 	<ul style="list-style-type: none"> • Submit information on disposal methods, clarify • Mailed a follow-up letter 	Loyda Meléndez, Ph.D
Susan Corey, Ph.D "qPCR of Na Pump Expression in Morphine Tolerance" (Reviewed: March 4, 2004)	NOT APPROVED: <ul style="list-style-type: none"> • Chemical list incomplete, do not include morphine and naloxone • Does not describe how to handle/dispose nor appropriate storage of chemicals • Does not include if the MSDS are on file • E. coli is not listed in Section A (page 3) • Certificate of being free of disease should be submitted • Section E should be... • Does not evidence that personnel involved with procedures are qualified or trained. (No training Certificates) • Tissues are being used and need to be included • Treatment of Retinoic Acid not clear in UV need to include protection by UV • Does not explain a Brief overview and its goal • No SOP's Included 	<ul style="list-style-type: none"> • Complete Chemical list • Describe how will chemicals be handled/disposed and stored • Include if the MSDS are on file • List E coli in Section A (page 3) • Submit Certificate of being free from disease (Section E) • Include evidence of qualified or trained personnel involved with procedures (Training Certificates) • Include Tissues being used • Include Treatment of Retinoic Acid and protection by UV • Explain the Brief overview and its goal • Include SOP's • Include DNA to be used • Include Cell Line Neuroblastoma to be used • Include animal list • Mailed a follow-up letter 	Loyda Meléndez, Ph.D

	<ul style="list-style-type: none"> • States that will not use DNA then indicates DNA will be used • Cell Line Neuroblastoma • Does not include anil list 		
Valrie Wojna, Ph.D "Oxidative Markers In HIV Dementia" (Reviewed: March 4, 2004)	NOT APPROVED: <ul style="list-style-type: none"> • Did not include SOP's • Did not include abstract and methods • Location of Work – specify Building (Neuro Aids) • Did not specify disposal method • Did not describe or specify infectious agents • Did not include training certificates of laboratory personnel 	<ul style="list-style-type: none"> • Include SOP's • Submit abstract and methods • Specify Building (Neuro Aids) • specify disposal method • Describe or specify infectious agents • include training certificates of laboratory personnel • Include evidence of qualified or trained personnel involved with procedures (Training Certificates) • Mailed a follow-up letter 	Loyda Meléndez, Ph.D
Valerie Wojna, Ph.D "Oxidative Markers In HIV Dementia" (Reviewed: March 04, 2004)	NOT APPROVED: <ul style="list-style-type: none"> • Did not include SOP for dealing with HIV-infected blood • Dinitrophenyl-hydrazine (Not on list) See page 2(2.b) • What is equitable waste and who conducts it? • What about Enid Castillo and Marines Plaud training evidence. • HIV – Infected Blood SOP missing. 	<ul style="list-style-type: none"> • Include: <ul style="list-style-type: none"> • SOP for HIV-infected blood • Dinitrophenyl-hydrazine • Definition of equitable waste and who conducts it? • Certificates of training • Mailed follow-up letter 	Loyda Meléndez, Ph.D
Loyda M. Meléndez, Ph.D (Progress Report) "Monocyte Immunity and HIV Dementia" (Reviewed: March 4, 2004)	APPROVED		BioSafety Committee
NEW PROTOCOLS:			

Serrano, Adelfa E. "Molecular Mechanisms of Multidrug Resistance in Rodent Malaria" (Reviewed March 25, 2004)	NOT APPROVED: <ul style="list-style-type: none"> No evidence provided of test or seminar of qualified and trained personnel that will be involved with procedures Need signature of the Department Chair 	<ul style="list-style-type: none"> Pending for an Administrative Approval once all documents required are submitted. Add signature of the Department Chair to the Biosafety Form Mailed follow up letter 	Loyda Meléndez, Ph.D
Meléndez, Loyda M. "Protein profiling of putative antiretroviral factors in placental macrophages" (Reviewed March 25, 2004)	NOT APPROVED: <ul style="list-style-type: none"> Sec. B – Storage –must be more specific Sec. C – Two people don't have training Sec. E – Same paragraph 	<ul style="list-style-type: none"> Specify in which type of cabinet the reagents will be stored Submit training certificates More specific on each paragraph on Sec.E Mailed follow up letter 	Loyda Meléndez, Ph.D
Lavergne, Julio A. "Evaluation of Potential Test of Clinical Mitochondrial Toxicity" (Renewal) (Reviewed March 25, 2004)	APPROVED	<ul style="list-style-type: none"> APPROVED 	BioSafety Committee

New Matters:

- **The OSHA Lab Standard and the RCM Chemical Safety Manual** – Committee Members will revise document.
- **Encijar Hassan Ríos, Doctoral Student, in Public Health** – "Asociación entre la exposición al plomo en sangre y el funcionamiento cognoscitivo en niños y adolescents residents de Brisas del Rosario del Municipio de Vega Baja Puerto Rico" - Blood samples will be taken out of the campus facilities. The committee recommends asking certification of the Laboratory and submit proposal for IRB and HIPAA approval.

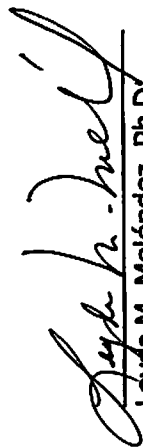
Pending for the Committee:

- A form will be prepared by Dr. Cadilla for samples that will be sent to other institutions for testing as part of the projects.

Committee Member's Suggestions:

- Dr. Melween Martinez recommends having an extraordinary meeting to define the politics of the Committee.

Meeting ended at 1:30 PM



Loyda M. Meléndez, Ph.D.
Professor and Chairperson
Biosafety Committee

Minutes taken By: Margarita Reyes Rivera

Approved by IBC on 3-25-04

BIOSAFETY COMMITTEE**Chairperson:** Loyda Meléndez, Ph.D**Date:** April 22, 2004**Next Meeting:** June 10, 2004**Location:** John B. Grant**Time:** 11:00 AM**Members**

Bloom Oquendo, Joseph Ph.D
 Cadilla Vázquez, Carmen Ph.D
 Martínez Rodríguez, Melween DVM
 Meléndez Aponte, Loyda Ph.D
 Robledo Burgos, Iralda E., Ph.D
 Robles Pereira, José A. MPH
 Rodríguez Orengo, José F. Ph.D
 Rodríguez Sierra, Carlos J. Ph.D
 Jiménez Fossé, Vanessa MPH

Members Present

Cadilla Vázquez, Carmen Ph.D
 Jiménez Fossé, Vanessa MPH
 Martínez Rodríguez, Melween DVM
 Meléndez Aponte, Loyda Ph.D
 Robledo Burgos, Iralda E., Ph.D
 Robles Pereira, José A. MPH

Members Excused

Bloom Oquendo, Joseph Ph.D
 Rodríguez Sierra, Carlos J. Ph.D
 Rodríguez Orengo, José F. Ph.D

Guest

TOPIC	DISCUSSION/CONCLUSION	ACTION/RECOMMENDATION	RESPONSIBILITY
Approval of Minutes		APPROVED	BioSafety Committee
NEW PROTOCOLS: Rodriguez,N. "Studies on the Dimorphism of Sporothrix Schenkii"	Primary Reviewer was absent Secondary Reviewer did not receive the proposal	• PENDING OF REVIEWERS	Primary Reviewer: Joseph Bloom, Ph.D. Secondary Reviewer: Carmen Cadilla, Ph.D.
Rosenthal, Joshua "Species-Dependent Regulation of Excitability by RNA Editing"	Secondary Reviewer was absent Primary Reviewer indicated that SOP are missing. Will request them from the PI	• PENDING OF SECONDARY REVIEWER'S COMMENTS	Primary Reviewer: Carmen Cadilla Vazquez, Ph.D. Secondary Reviewer: Jose Rodriguez-Orengo, Ph.D.
Wojna , Valerie "Oxidative Markers in HIV Dementia" (Reviewed: March 4, 2004)	Submitted all documents requested by the Committee	• APPROVED	Primary Reviewer: Joseph Bloom Oquendo, Ph.D. Secondary Reviewer: Carlos Rodriguez, Ph.D.

New Matters:

- **A New Secretary is needed for the Committee. Ms. Margarita Reyes left to the US for Personal reasons.**

Pending for the Committee:

- A form will be prepared by Dr. Cadilla for samples that will be sent to other institutions for testing as part of the projects.
- **The OSHA Lab Standard and the RCM Chemical Safety Manual** –Pending documents from some Committee members.
- Dr. Melween Martinez will meet with Dr. Meléndez on June 9 to define the politics of the Committee.
- The committee suggested appointment of Vanessa M Rodríguez from CASSO to the Committee.

Meeting ended at 1:30 PM



Loyda M. Meléndez, Ph.D
Professor and Chairperson
Biosafety Committee

Minutes taken By: Loyda M. Meléndez

BIOSAFETY COMMITTEE**Chairperson:** Loyda Meléndez, Ph.D**Date:** June 10, 2004**Next Meeting:** August 13, 2004**Location:** 10th floor Main Building**Time:** 11:00 AM**Members**

Bloom Oquendo, Joseph Ph.D
 Cadilla Vázquez, Carmen Ph.D
 Martínez Rodríguez, Melween DVM
 Meléndez Aponte, Loyda Ph.D
 Robledo Burgos, Iralda E., Ph.D
 Robles Pereira, José A. MPH
 Rodríguez Orengo, José F. Ph.D
 Rodríguez Sierra, Carlos J. Ph.D
 Jiménez Fossé, Vanessa MPH

Members Present

Jiménez Fossé, Vanessa MPH
 Martínez Rodríguez, Melween DVM
 Meléndez Aponte, Loyda Ph.D
 Robledo Burgos, Iralda E., Ph.D
 Martínez, Idali, Ph.D.
 Segarra, Annabel, Ph.D.

Members Excused

Bloom Oquendo, Joseph Ph.D
 Cadilla Vázquez, Carmen Ph.D
 Rodríguez Sierra, Carlos J. Ph.D
 Rodríguez Orengo, José F. Ph.D
 Robles Pereira, José A. MPH

Guest

TOPIC	DISCUSSION/CONCLUSION	ACTION/RECOMMENDATION	RESPONSIBILITY
Approval of Minutes			BioSafety Committee
NEW PROTOCOLS: Rodriguez,N. "Studies on the Dimorphism of Sporothrix Schenkii"	Primary Reviewer was absent Secondary Reviewer did not receive the proposal	• APPROVED (Reviewers sent their comments by e-mail)	Primary Reviewer: Joseph Bloom, Ph.D. Secondary Reviewer: Carmen Cadilla, Ph.D.
Rosenthal, Joshua "Species-Dependent Regulation of Excitability by RNA Editing"	Secondary Reviewer was absent Primary Reviewer indicated that SOP are missing. Will request them from the PI	• APPROVED (Reviewers sent their comments by e-mail)	Primary Reviewer: Carmen Cadilla Vazquez, Ph.D. Secondary Reviewer: Jose Rodriguez-Orengo, Ph.D.

Maria Sosa, Ph.D. "Crustacean aminergic gene expression as a function of dominance status"	<p>Include:</p> <ul style="list-style-type: none"> -Certain chemicals such as acrylamide and sodium thiocyanate in parts B and E of the form. -E. coli in the list of infectious agents. Specify strain and Biosafety Level. 	<ul style="list-style-type: none"> • NOT APPROVED 	<p>Primary Reviewer: Loyda Melendez, Ph.D.</p> <p>Secondary Reviewer: Iralda Robledo, Ph.D</p>
Ana Espino, Ph.D. "Characterization of T and B-cell epitopes of multiple antigenic peptides for a Fasciola/Schistosoma cross-reactive vaccine"	<p>Include:</p> <ul style="list-style-type: none"> -Certain chemicals such as acrylamide, sodium thiocyanate, sulfuric acid, and nitrocellulose in parts B and E of the form. -Submit to IRB and HIPAA if human samples are included. -Evidence of Hepatitis B vaccine and Blood borne pathogens training to the personnel. - Provide evidence of Biosafety training or take exam by the web. - Specify how the metacercariae will be irradiated and include safety precautions. 	<ul style="list-style-type: none"> • NOT APPROVED 	<p>Primary Reviewer: Iralda Robledo, Ph.D.</p> <p>Secondary Reviewer: Loyda Meléndez, Ph.D.</p>
Nitza Lugo, Ph.D. "The NPY and GABA expression in the aging ground squirrel circadian system" (amendment)		<ul style="list-style-type: none"> • APPROVED 	

New Matters:

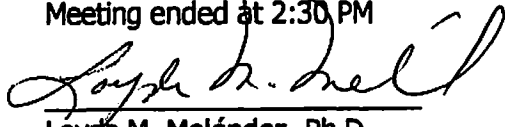
- Dra. Idalí Martínez was welcome to the Committee as a new alternate member for Dr. Carmen Cadilla since her expertise is also on recombinant DNA.
- A Secretary was interviewed by Dr. Meléndez and Dr. Annabell Segarra for the Committee.

- Dr. Melween Martinez met with Dr. Meléndez on June 9 to define the politics of the Committee. A draft was presented at the meeting and will be discussed in the August 13, meeting.

Pending for the Committee:

- A form will be prepared by Dr. Cadilla for samples that will be sent to other institutions for testing as part of the projects.
- **The OSHA Lab Standard and the RCM Chemical Safety Manual** –Pending documents from two Committee members.

Meeting ended at 2:30 PM



Loyda M. Meléndez, Ph.D
Professor and Chairperson
Biosafety Committee

Minutes taken By: Loyda M. Meléndez

Approved on August 26, 2004 meeting

BIOSAFETY COMMITTEE**Chairperson:** Julio A. Lavergne, Ph.D**Date:** December 9, 2004**Next Meeting:** February 10, 2005**Location:** Chancellor's Conference**Time:** 11:00am – 1:00pm**Members**

Julio Lavergne, Ph.D.
 Loyda Meléndez, Ph.D.
 Ms. Judith Tenant
 Mr. Jimmy Drowne
 Joseph Bloom, Ph.D.
 Idali Martínez, Ph.D.
 Ms. Vanesa Jiménez Fosse
 Melween Martínez, DVM
 Iraida Robledo, Ph.D.
 José A. Robles, MPH
 Carlos Rodríguez, Ph.D.
 Carlos Sariol, MD
 Idith R. Ortiz, MD, Ph.D.

Members Present

Joseph Bloom, Ph.D.
 Ms. Judith Tenant
 Julio Lavergne, Ph.D.
 Idali Martínez, Ph.D.
 Melween Martínez, DVM
 Iraida Robledo, Ph.D.
 Carlos Sariol, MD
 Carlos J. Rodríguez, Ph.D.
 José A. Robles, MPH
 Damarith Díaz Aponte, MPH

Members Excused

Loyda Meléndez, Ph. D.
 Ms. Vanessa Jiménez Fosse

Guest

Dr. Luis J. Torres Bauzá

TOPIC	DISCUSSION / CONCLUSION	ACTION
Approval of Minutes		
Approval of minutes from the last meeting.		Approved.
Response to letters sent on November 23, 2004 were received from: - Abraham Schwartz, Ph. D. "Development of a Transgenic cichlid Model for Diabetes-Related Studies"	-All questions were addressed and answered satisfactorily.	Proposal was approved.

TOPIC	DISCUSSION/CONCLUSION	ACTION
- Luis Torres-Bauzá, Ph. D. "Molecular Analysis of multiple orit's in the gonococcal mobilizable R plasmids".	- Certification of training for technician and student are pending.	Proposal was approved conditioned to provision of certifications.
The following proposals are still pending for approval by the Committee: - Clemente Díaz, M.D. "Women and Infant Transmission study". - Rosimar Torres, M.D. "PR CCHD Pilot Study #1: Adaptation and Piloting of an HIV Prevention Intervention utilizing the rapid HIV Test in Women at risk for HIV". - Benjamín Bolaños, Ph. D. "Activities of Amphotericin B, Caspofungin, Fluconazole, Itraconazole and Voriconazole against recent clinical isolates of Candida spp from Puerto Rico".	Must answer issues stated in letter sent by the Committee. Must answer issues stated in letter sent by the Committee. Must answer issues stated in letter sent by the Committee.	Pending of approval. Pending of approval. Pending of approval.
New Matters: 1. Method for the identification of Proposals submitted to the Committee. 2. Progress report from the office of Safety for Research Laboratories: -Work plan -Directory of Laboratories -Chemical Inventory -Inspection of Lab. B-221 -Picric Acid disposal in Lab. A-1067 3. Progress report of the Committee to the NIH 4.Next meeting of the Committee. 5.Operating budget of the Committee.	Will consult with Dr. Loyda Meléndez. Presented by Lic. Damarith Díaz Aponte. Drs. Torres-Bauzá, Meléndez and Lavergne will meet to prepare it on Dec. 17, 2004 Will be discussed in the following meetings of the Committee.	Pending. Received by the Committee. Progress Report was sent to the NIH on Dec. 21, 2004. Scheduled for February 10, 2005. Pending.

The meeting ended at 1:30pm.

Julio A. Lavergne, Ph. D
Professor and Chairperson
Institutional Biosafety Committee

Minutes taken by: Julio A. Lavergne, Ph. D.

Approved in:
/mmc


02/10/2005

BIOSAFETY COMMITTEE**Chairperson:** Julio A. Lavergne, Ph.D**Date:** February 10, 2005**Next Meeting:** March 10, 2005**Location:** Conference room 173b Biomed 1**Time:** 11:00am – 1:00pm**Members**

Julio Lavergne, Ph.D.
 Jossian Pagán Lisboa, MS
 Ms. Judith Tenant
 Mr. Jimmy Drowne
 Joseph Bloom, Ph.D.
 Idali Martínez, Ph.D.
 Ms. Vanesa Jiménez Fosse
 Melween Martínez, DVM
 Iraida Robledo, Ph.D.
 José A. Robles, MPH
 Carlos Rodríguez, Ph.D.
 Carlos Sariol, MD
 Idith R. Ortiz, MD, Ph.D.

Members Present

Joseph Bloom, Ph.D.
 Jossian Pagán Lisboa, MS
 Julio Lavergne, Ph.D.
 Idith Ortiz, MD, MPH
 Melween Martinez, DVM
 Iraida Robledo, Ph.D.
 Carlos Sariol, MD
 Carlos J. Rodríguez, Ph.D.
 José A. Robles, MPH

Members Excused

Idali Martínez, MD, MPH
 Ms. Vanessa Jiménez Fosse

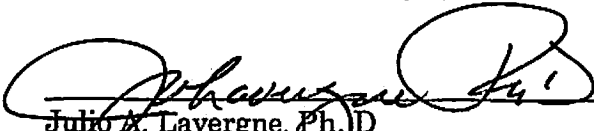
Guest

Dr. Luis J. Torres Bauzá
 Damarith Díaz Aponte

TOPIC	DISCUSSION / CONCLUSION	ACTION
Approval of Minutes		
Approval of minutes from the last meeting.		Approved.
Letter of approval for Dr. Abraham Schwartz, Ph. D.	-His dateline after proposal approval is November 09, 2005.	Letter of approval was sent.

<p>The following proposals were approved:</p> <p>SOURCE: IBC Archive</p> <ul style="list-style-type: none"> - Rosimar Torres, M.D. "PR CCHD Pilot Study #1: Adaptation and Piloting of an HIV Prevention Intervention utilizing the rapid HIV Test in Women at risk for HIV". - Benjamín Bolaños, Ph. D. "Activities of Amphotericin B, Caspofungin, Fluconazole, Itraconazole and Voriconazole against recent clinical isolates of <i>Candida</i> spp from Puerto Rico". - Luis Torres-Bauzá, Ph. D. "Molecular Analysis of multiple <i>oriT</i>'s in the gonococcal mobilizable R plasmids". 	<p>The Sunshine Project - FOI Fund www.sunshine-project.org</p> <ul style="list-style-type: none"> -All questions were addressed and answered satisfactorily. -All questions were addressed and answered satisfactorily. - All questions were addressed and answered satisfactorily. 	<p>Proposal was approved.</p> <p>Proposal was approved.</p> <p>Proposal was approved.</p>
<p>The following proposals are still pending for approval by the Committee:</p> <ul style="list-style-type: none"> - Clemente Díaz, M.D. "Women and Infant Transmission study". 	<p>Must answer issues stated in letter sent by the Committee.</p>	<p>Pending of approval.</p>
<p>Pending Matters:</p> <ol style="list-style-type: none"> 1. Progress report of the Committee to the NIH 2. Follow up on Dr. Anil Kumar's proposal 3. Progress on the Chemical Inventory 4. Next meeting of the Committee <p>New Matters:</p> <ol style="list-style-type: none"> 1. Update Website 2. Laboratory Waste management proposal 3. Progress report from the Office of Safety for Research Laboratories 	<p>The progress report was prepared to be send to the NIH.</p> <p>Dr. Martínez and Dr. Sariol presented the information that is missing to approve the proposal.</p> <p>Request for Committee members to provide final corrections and information.</p> <p>Possibility of actualize website was discussed for future use.</p> <p>Oscar Rohena's proposal was discussed.</p> <p>Reports concerning safety inspections in ACTU, Laboratory B-221 and high risk laboratories were presented.</p>	<p>The report was send.</p> <p>Letter will be send requesting necessary information to Dr. Kumar.</p> <p>Pending.</p> <p>Scheduled for March 10, 2005</p> <p>Approved.</p> <p>Request will be made to the Chancellor's office to obtain necessary funds.</p> <p>Pending</p>

The meeting ended at 1:00pm.


Julio A. Lavergne, Ph.D.
Professor and Chairperson
Institutional Biosafety Committee

Minutes taken by: Teresa Soto and Jossian Pagán.

Approved in:
/mmc



Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: March 10, 2005

Next meeting: April 14, 2005

Location: Animal Resource Center

Conference room

RCM building

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Ms. Judith Tennant
Joseph Bloom, Ph. D.
Idali Martínez, Ph. D.
Ms. Vanessa Jiménez Fosse
Melween Martínez, DVM
Iraida Robledo, Ph. D.
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Carlos Sariol, M.D.
Idith R. Ortiz, MD, Ph. D.

Members Present

Julio Lavergne, Ph. D.
Joseph Bloom, Ph. D.
Iraida Robledo, Ph. D.
Idali Martínez, Ph. D.
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Melween Martínez, DVM
Carlos Sariol, MD.
Jossian Pagán, MS
Idith Ortiz, MD. Ph. D.

Members Excused

Guests

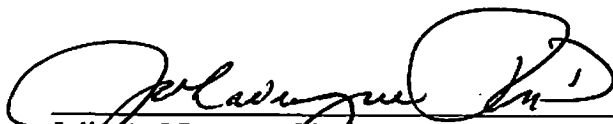
Damarith Díaz Aponte, MS
Dr. Luis J. Torres-Bauzá Ph. D.(Excused)

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
Letters of approval for Dr. Luis Torres-Bauzá, Dra. Rosimar Torres and Dr. Benjamín Bolaños.		Letters of approval were sent.

TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>The following proposal is still pending for approval:</p> <p>Clemente Díaz, MD “Women and Infant transmission study”.</p> <p>Jorge L. Santana, MD “A5197: A Phase II, double-blind, randomized, placebo-controlled study to evaluate the antiretroviral effect of immunization...”</p>	<p>Letter stating information that is missing to approve proposal and its deadline. (Carta Modelo)</p> <p>Several recommendations were discussed</p>	<p>Letter will be sent to Dr. Díaz requesting necessary information.</p> <p>Pending. Favorable to be approved if recommendations are applied.</p>
Letter to Chancellor Dr. José Carlo	Letter stating the approval from the NIH to register the Biosafety Committee.	Letter was sent.
<p>Pending Matters:</p> <p>1. Follow up on Dr. Anil Kumar’s proposal</p> <p>2. Progress on the Chemical Safety Manual</p> <p>3. Next meeting of the Committee</p>	<p>Copies of the manual will be provided to identify and evaluate sections that need to be corrected</p>	<p>Follow up will be done thru e-mail and phone call.</p> <p>Pending</p> <p>Scheduled for April 14, 2005</p>
<p>New Matters:</p> <p>1. Follow up on the IBC Website</p> <p>2. Laboratory Waste Management Proposal</p> <p>3. Follow up on the Biosafety Inspection at the ACTU project</p> <p>4. Follow up on the progress report from the office of Safety for Research Laboratories</p>	<p>Revision of Manuals to be announced on the Website</p> <p>Letter was sent to the Chancellor, Dr. José Carlo to obtain necessary funds</p> <p>Copies of the Research Directory will be provided. Dates for next trainings on Biosafety and Chemical Substances handling were provided</p>	<p>Pending</p> <p>Pending</p> <p>Necessary training was provided</p> <p>Pending</p>

5. Follow up on the Progress Report of Laboratory B-221	Mrs. Damarith Díaz is following up on the matter	Pending
6. Health related personnel wearing lab coats in food court areas	Matter has to be addressed to the proper channels	Pending

The meeting ended at 2:10 p.m.


 Julio A. Lavergne, Ph. D.
 Professor and Chairperson
 Institutional Biosafety Committee
 04/14/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE
Chairperson: Julio A. Lavergne, Ph. D.
Date: April 14, 2005

Next meeting: May 12, 2005
Location: Animal Resources Center
Conference room RCM building
Time: 11:00 am -1:00 pm

Members	Members Present	Members Excused	Guests
Julio Lavergne, Ph. D.	Julio Lavergne, Ph. D.	Idith Ortiz, MD, Ph. D.	Luis J. Torres-Bauza, Ph. D.
Jossian Pagán, MS	Jossian Pagán, MS		Damarith Díaz Aponte, MS
Joseph Bloom, Ph. D.	Joseph Bloom, Ph. D.		
Idali Martínez, Ph. D.	Idali Martínez, Ph. D.		
Melween Martínez, DVM	Melween Martínez, DVM		
Iraida Robledo, Ph. D.	Iraida Robledo, Ph. D.		
José A. Robles, MPH	José A. Robles, MPH		
Carlos Rodríguez, Ph. D.	Carlos Rodríguez, Ph. D.		
Carlos Sariol, M.D.	Carlos Sariol, M.D.		
Idith R. Ortiz, M.D., Ph. D.			

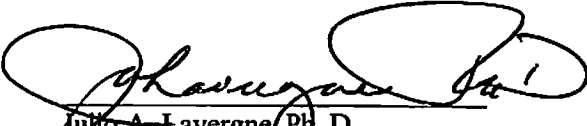
Meeting started at 11:22 am

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting	Make certain corrections to the text.	Approved after corrections are made.

<p>The following proposal is still pending for approval: Dr. Jorge L. Santana Project A5197 "A Phase II, Double Blind, Randomized Placebo Controlled Study"</p>	<p>Important information that is missing needs to be provided in order to approve the project. Ex. safety precautions details, procedures to be used during the handling of vaccines, disposal of chemicals and other types of waste.</p>	<p>Letter will be send requesting necessary information.</p>
<p>Pending Matters</p> <ol style="list-style-type: none"> 1. Follow up on Carmen Zorrilla's proposal (CEMI) 2. Progress on the Chemical Safety Manual. 3. Progress on the revision of the Chemical Hygiene Plan, General Plan and the Hazard Communication Program. 4. Next meeting of the Committee. 5. Identify Clinical and Research laboratories. 6. Follow up on the progress report of Laboratory B-221 7. Follow up on the progress report from the Office of Safety for Research Laboratories. 8. Follow up on health related personnel wearing lab coats in food court areas 	<p>Dr. Carlos Rodríguez and Dr. Joseph Bloom are revising the Manual. Two copies of two other manuals from the American Chemical Society were brought to have as a guide.</p> <p>They can be posted on the Committee website specifying that all three manuals are under revision. Copies will be divided among members to revise and make necessary corrections.</p> <p>This was discussed in a meeting with the Dean of Administration, Mr. Irving Jiménez.</p> <p>Mrs. Damarith Díaz is following up on the matter.</p> <p>After the Chemical waste in laboratories is disposed, there should be more control over the quantities of Chemicals that are purchased in laboratories.</p>	<p>Letter requesting missing information was sent. Pending until a response is received.</p> <p>Pending</p> <p>Pending</p> <p>Scheduled for May 12, 2005.</p> <p>A plan to identify the laboratories will be made.</p> <p>A storage cabinet was provided; some chemicals were placed in a safer area.</p> <p>This will help to minimize the amounts of chemical waste to be disposed.</p> <p>A letter was sent to Dr. Ana María Díaz, School of Medicine Senator, addressing the situation.</p>

<p>New Matters:</p> <ol style="list-style-type: none"> 1. Dr. Carlos Rodríguez new proposal "Trace metals in sportfish, sediment and water of Humacao Natural Reserve" 2. Replacement of two community members of the Committee. 3. Emergency phone numbers to be distributed and posted in laboratories. 4. Renewal of license for the use of chemicals in laboratories. 	<p>Dr. Julio Lavergne and Dr. Joseph Bloom are the reviewers.</p> <p>Newspaper announcement has to be made to notify the community.</p> <p>Emergency phone number should be of the person in charge of laboratory or work area. Must be placed on the laboratory door, visible to all personnel.</p> <p>This matter has to be addressed to Mr. Irving Jiménez.</p>	<p>Will be discussed on the next meeting.</p> <p>Pending</p> <p>Pending.</p> <p>Pending.</p>

Meeting ended at 1:11 pm


 Julio A. Lavergne Ph. D.
 Professor and Chairperson
 Institutional Biosafety Committee

05/12/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: May 12, 2005

Next meeting: June 9, 2005

Location: Animal Resources Center

Conference room RCM building

Time: 11:00 am -1:00 pm

Members

Julio Lavergne, Ph. D.
Jossian Pagán, MS
Joseph Bloom, Ph. D.
Idalí Martínez, Ph. D.
Melween Martínez, DVM
Iraida Robledo, Ph. D.
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Carlos Sariol, MD
Idith R. Ortiz, MD, MPH.

Members Present

Julio Lavergne, Ph. D.
Carlos Sariol, MD
Joseph Bloom, Ph. D.
Idalí Martínez, Ph. D.
Melween Martínez, DVM
Iraida Robledo, Ph. D.
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Idith Ortiz, MD, MPH.

Members Excused

Jossian Pagán, MS

Guests

Damarith Díaz Aponte, MS

Meeting started at 11:30 am

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved

<p>The following proposals are still pending for approval: Dr. Jorge L. Santana Project A5197 “A Phase II, Double Blind, Randomized Placebo Controlled Study”</p> <p>Dr. Carlos Rodríguez-Sierra “Trace metals in sportsfish, sediment and water of Humacao Natural Reserve”.</p>	<p>A response letter from Dr. Santana was received during today’s Committee meeting.</p> <p>The reviewers, Dr. Lavergne and Dr. Bloom found the information presented in the proposal to be in order and complete. Only evidence of personnel training is missing.</p>	<p>The letter will be evaluated in the next Committee meeting.</p> <p>Evidence of trained personnel was requested.</p>
<p>Pending Matters</p> <ol style="list-style-type: none"> 1. Follow up on Dr. Clemente Díaz proposal “Women and Infant Transmission study” 2. Follow up on Dr. Carmen Zorrilla’s proposal (CEMI) Project 1350205 3. Progress on the Chemical Safety Manual. 4. Progress on the revision of the Chemical Hygiene Plan, General Plan and the Hazard Communication Program. 5. Next meeting of the Committee. 	<p>A Memorandum letter was sent on May 11, 2005 to Dr. Díaz.</p> <p>Letter requesting missing information was send on March 31, 2005. Dr. Zorrilla sent a response letter with the SOP and evidence of trained personnel. There was still a certificate of training missing.</p> <p>Dr. Carlos Rodríguez and Dr. Joseph Bloom are still in the process of revising the Manual.</p> <p>The Chemical Hygiene Plan was divided among members for revision*. The General Plan and the Hazard Communication Program will be revised after the Chemical Hygiene Plan and the Chemical Safety Manual are revised and corrected.</p>	<p>Pending until a response is received.</p> <p>Dr. Lavergne notified by phone the document that is required. Pending until a response is received.</p> <p>Pending</p> <p>Pending</p> <p>Scheduled for June 22, 2005.</p>

6. Identify Clinical and Research laboratories.	A form will be made to identify Research laboratories.	Pending
7. Follow up on the progress report of Laboratory B-221.	Mrs. Damarith Díaz is following up on the matter.	A remodeling job will start at Dr. Antoun's laboratory in the next few weeks. It was recommended to remove or relocate the chemicals before the construction starts.
8. Follow up on the progress report from the Office of Safety for Research Laboratories.	Emergency equipment (eyewash and showers) has been installed in several laboratories. For the chemical waste removal in laboratories, three price quotations from Waste removal companies were presented for revision.	Progress has been made. Mr. Oscar Rohena's consulting contract and funds for the removal of chemicals have been approved.
9. Replacement of two community members of the Committee.	Filed information and resumes of community members that were not accepted in the past, will be reviewed.	Pending
10. Committee 'By laws' revision.	Copies of the 'By laws' were handed to members.	Will be discussed on the next meeting.
11. Renewal of license for the use of explosive chemicals in laboratories.	A plan is under development for the Investigators to be able to renew their licenses. Two lists of explosive chemicals that were provided by the local police have to be revised.	Pending
New Matters		
RCMI program, 2000 not approved proposals	Dr. Lavergne will get in contact with the investigators and Mr. Braulio Jiménez to clarify and obtain more information.	Pending

*Introduction page 3 section 1.0 - page 13 section 13.0 revised by Dr. Lavergne

Page 13 section 14.0 – page 24 revised by Dr. Bloom

Page 25 – page 34 revised by Dr. Robledo

Page 35 – page 46 revised by Dr. I. Martínez

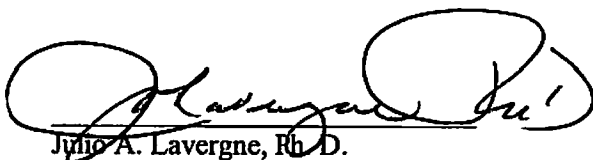
Page 47 – page 57 revised by Mr. Robles

Page 58 – page 67 revised by Dr. Rodríguez

Page 68 – page 78 revised by Mrs. M. Martínez

Page 79 – page 83 revised by Dr. Sariol

Meeting ended at 1:30 pm

A handwritten signature in black ink, appearing to read 'Julio A. Lavergne', with a large, stylized flourish at the end.

Julio A. Lavergne, Ph.D.

Professor and Chairperson

Institutional Biosafety Committee

06/09/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: June 22 2005

Next meeting: August 11, 2005

Location: Animal Resource Center

Conference room

RCM building

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Idith Ortiz, MD, MPH.

Members Present

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
Idith Ortiz, MD, MPH
Carlos Sariol, MD.

Members Excused

Joseph Bloom, Ph. D.
Carlos Rodríguez, Ph. D.
José A. Robles, MPH

Guests

Damarith Díaz Aponte, MS (*excused*)
Dr. Luis J. Torres-Bauzá Ph. (*excused*)
Lcda. María I. Roque Espina
Lcda. María Teresa Rodríguez

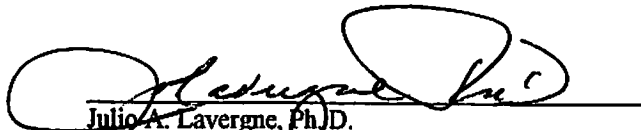
Meeting started at 11:55 am

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
<p>The following proposals were approved: Carmen Zorrilla, MD "Proyect 1350205"</p> <p>Jorge L. Santana, MD "A5197: A Phase II, double-blind, randomized, placebo-controlled study to evaluate the antiretroviral effect of inimmunization..."</p>	Dr. Zorrilla sent document that was missing for approval of her proposal.	<p>Letter of approval was sent.</p> <p>Letter of approval was sent.</p>

Carlos Sariol, MD. Two proposals		Approved
TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>The following proposals are still pending for approval:</p> <p>Clemente Díaz, MD "Women and Infant transmission study".</p> <p>Dr. Carlos Rodríguez-Sierra "Trace metals in sportsfish, sediment and water of Humacao Natural Reserve".</p> <p>Dr. Annabell Segarra "Estrogen and cocaine sensitization in the female rat"</p>	<p>A Memorandum letter was sent to Dr. Díaz on May 11, 2005. No response has been received.</p> <p>Reminder to provide evidence of trained personnel.</p> <p>Proposal is incomplete.</p>	<p>The letter will be resend to Dr. Díaz. requesting necessary information. Pending until a response is received.</p> <p>Pending.</p> <p>Pending.</p>
<p>Pending Matters:</p> <p>1. Progress on the Chemical Safety Manual</p> <p>2. Progress on the revision of the Chemical Hygiene Plan.</p> <p>3. Committee 'By-laws' revision</p> <p>4. Replacement of two community members of the Committee.</p>	<p>Dr. Rodríguez and Dr. Bloom are still revising the manual.</p> <p>Still under revision by the members of the committee.</p> <p>A sub-committee was created to revise the 'By-laws'. Members are: Dr. Melween Martínez, Dr. Iraida Robledo, Dr. Idali Martínez and Dr. Julio Lavergne.</p> <p>Dr. Lavergne recommended Mrs. María Teresa Rodríguez and Mrs. María I. Roque They were invited to the meeting.</p>	<p>Pending</p> <p>Pending</p> <p>Pending</p> <p>They cordially accepted the invitation to become the new community members.</p>

5. Identify Clinical and Research laboratories.	A form will be made to identify them.	Pending
6. Renewal of license for the use of explosive chemicals in laboratories.	Certain details have to be verified with the Dean of Administration, Mr. Irving Jiménez.	Pending
7. Progress report from the Office of Safety for Research Laboratories.		Presented and received by the committee.
8. Next meeting of the Committee		August 11, 2005
New Matters:		
1. Recombinant DNA Guidelines	An inquiry will be made to verify if training for this can be provided.	Pending

The meeting ended at 1:35 pm


 Julio A. Laverne, Ph.D.
 Professor and Chairperson
 Institutional Biosafety Committee
 08/11/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: August 11, 2005

Next meeting: September 8, 2005

Location: Animal Resource Center

Conference room

RCM building

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idalí Martínez, Ph. D.
Melween Martínez, DVM
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Idith Ortiz, MD, MPH.
María I. Roque Espina, MS
María T. Rodríguez, MS
Carlos Sariol, MD

Members Present

Julio Lavergne, Ph. D.
José A. Robles, MPH
Iraida Robledo, Ph. D.
Idalí Martínez, Ph. D.
Melween Martínez, DVM
Idith Ortiz, MD, MPH
María I. Roque, MS
María T. Rodríguez, MS
Carlos Rodríguez, Ph D.

Members Excused

Jossian Pagán, MS
Carlos Sariol, MD

Guests

Damarith Díaz Aponte, MS (excused)
Dr. Luis J. Torres-Bauzá Ph. (absent)

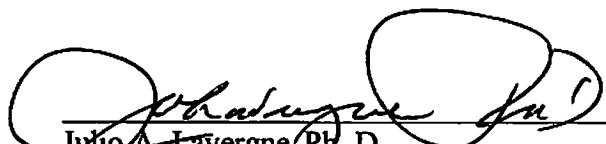
Meeting started at 11:28 am

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
The following proposal was presented: Irma L. Febo, MD "PACTG P1059"	Two committee members were chosen as the primary and secondary reviewers.	Protocol will be reviewed on the next meeting.

TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>The following proposals are still pending for approval:</p> <p>Dr. Clemente Díaz, "Women and Infant transmission study".</p> <p>Dr. Carlos Rodríguez-Sierra "Trace metals in sportfish, sediment and water of Humacao Natural Reserve".</p> <p>Dr. Annabell Segarra "Estrogen and cocaine sensitization in the female rat".</p>		<p>An e-mail will be sent to Dr. Díaz.</p> <p>A letter will be send to Dr. Rodríguez.</p> <p>A letter will be sent to Dr. Segarra requesting necessary information that is missing to approve her proposal.</p>
<p>Pending matters:</p> <p>Progress on the Chemical Safety manual</p> <p>Progress on the Chemical Hygiene Plan</p> <p>Committee 'By-laws' revision</p> <p>Identify Clinical and Research laboratories.</p> <p>Renewal of license for the use of explosive chemicals in laboratories.</p> <p>Progress report from the Office of Safety for Research Laboratories</p> <p>Recombinant DNA Guidelines</p> <p>Next meeting of the Committee</p>	<p>Still under revision by members of the committee.</p> <p>Still under revision by members of the committee.</p> <p>Still under revision by members of the committee.</p> <p>Mr. José A. Robles gave a briefing of the high hazard waste pick up in laboratories, performed by Clean Harbors company.</p> <p>NIH does not provide training. Dr. Idali Martínez will inquire about the matter.</p>	<p>Pending</p> <p>Pending</p> <p>Pending</p> <p>Pending</p> <p>Pending</p> <p>Presented and received by the committee.</p> <p>September 8, 2005</p>

TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>New matters: Revision of Committee Protocols</p>	<p>Dr. Idali Martínez, Dr. Melween Martínez and Dr. Iraidá Robledo revised and submitted several corrections and changes, to be implemented regarding protocol revision.</p>	<p>New forms will be presented to committee members for final revision and corrections.</p>
<p>Biological waste exposed in an area near the Pediatric Hospital.</p>	<p>Mr. José A. Robles presented the situation to the committee.</p>	<p>He will inquire about which department the issue should be addressed.</p>
<p>Pending protocols which primary investigators have not provided a response to the committee.</p>	<p>The protocol could start or proceed without the committee approval or knowledge. A time extension could be provided to render a response to the committee.</p>	<p>The issue has to be presented to the Dean of Administration and to Dr. Luis Torres-Bauza. Dr. Lavergne will follow up on the matter.</p>

The meeting ended at 1:46 pm


 Julio A. Lavergne, Ph. D.
 Profesor and Chairperson
 Institutional Biosafety Committee

09/08/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: September 8, 2005

Next meeting: October 13, 2005

Location: Animal Resources Center

Conference room

RCM building, 10th Floor

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idalí Martínez, Ph. D.
Melween Martínez, DVM
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Idith Ortíz, MD, MPH.
María I. Roque Espina, MS
María T. Rodríguez, MS
Carlos Sariol, MD

Members Present

Julio Lavergne, Ph. D.
José A. Robles, MPH
Jossian Pagán Lisboa, MS
Idalí Martínez, Ph. D.
Melween Martínez, DVM
Idith Ortíz, MD, MPH
María T. Rodríguez, MS

Members Excused

Carlos Rodríguez, Ph. D.
Carlos Sariol, MD
María I. Roque, MT
Iraida Robledo, Ph. D.

Guests

Damarith Díaz Aponte, MS (excused)
Dr. Luis J. Torres-Bauzá Ph. (absent)

Meeting started at 11:30 am

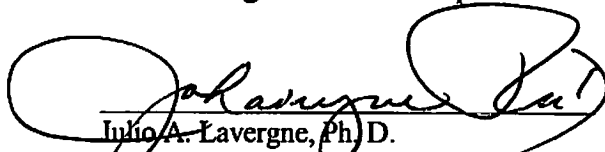
TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
The following proposal was presented: Dr. Carmen Zorrilla, MD "HVTN Protocol 403"	Two members were chosen to review the protocol.	Protocol will be discussed on the next meeting.

TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>The following proposals are still pending for approval:</p> <p>Irma L. Febo, MD "PACTG P1059"</p> <p>Dr. Carlos Rodríguez-Sierra "Trace metals in sportsfish, sediment and water of Humacao Natural Reserve".</p> <p>Dr. Annabell Segarra "Estrogen and cocaine sensitization in the female rat".</p>	<p>Necessary information was missing regarding safety procedures, vaccine preparation and transportation among other details.</p>	<p>A letter stating information to be submitted for approval of the proposal will be sent.</p> <p>A letter will be send to Dr. Rodríguez requesting necessary information that is needed to approve his proposal.</p> <p>A letter will be sent to Dr. Segarra requesting necessary information that is missing to approve her proposal.</p>
<p>Pending matters:</p> <p>Progress on the Chemical Safety manual</p> <p>Progress on the Chemical Hygiene Plan</p> <p>Committee 'By-laws' revision</p> <p>Identify Clinical and Research laboratories. Renewal of license for the use of explosive chemicals in laboratories.</p>	<p>Still under revision by members of the committee.</p> <p>Still under revision by members of the committee.</p> <p>Dr. Melween Martínez requested a meeting with Dr. Lavergne to discuss the committee By-laws.</p>	<p>Pending</p> <p>Dr. Lavergne will arrange an extraordinary meeting with the committee members to revise it. Meeting was arranged.</p> <p>Pending</p>

Progress report from the Office of Safety for Research Laboratories	Mr. Jossian Pagán had a meeting with the Dean of Administration. Radiation issues, Laboratory investigation and Incinerator management should be covered by the Radiation Safety office.	Presented and received by the committee.
License for the use of Explosive Chemicals	Mr. Jossian Pagán gave a progress report.	A meeting with personnel from the local police dept. will be scheduled for Investigators to participate and clarify information.
Next meeting of the Committee		October 13, 2005

TOPIC	DISCUSSION/CONCLUSION	ACTION
New matters: Protocol presented from the San Juan Municipal Hospital.	Dr. Lavergne will inquire about the protocol theme and deadline. Since the Municipal Hospital does not fall under the MSC, the IBC could charge for the revision.	Dr. Lavergne will follow up on the matter.

The meeting ended at 1:35/ pm


Julio A. Lavergne, Ph.D.
Professor and Chairperson
Institutional Biosafety Committee
10/13/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: October 13, 2005

Next meeting: November 10, 2005

Location: Animal Resources Center

Conference room

RCM building, 10th Floor

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Idith Ortíz, MD, MPH.
María I. Roque Espina, MT
María T. Rodríguez, MT
Carlos Sariol, MD

Members Present

Julio Lavergne, Ph. D.
José A. Robles, MPH
Jossian Pagán Lisboa, MS
Idali Martínez, Ph. D.
Melween Martínez, DVM
Idith Ortíz, MD, MPH
María T. Rodríguez, MT
Carlos Rodríguez, Ph. D.
Carlos Sariol, MD
María I. Roque, MT
Iraida Robledo, Ph. D.

Members Excused

Joseph Bloom, Ph. D

Guests

Damarith Díaz Aponte, MS
Dr. Luis J. Torres-Bauzá Ph.
Nancy Ildefonso, Director CASSO
Luis Limas, Clean Harbors representative
Oscar Rohena, Environmental Consultant

Meeting started at 11:30 am

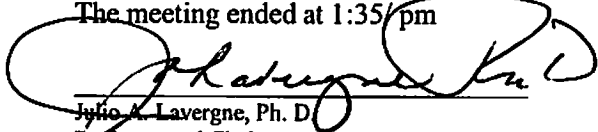
TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
New proposal: Dr. Carlos Sariol, "Immunogenicity of a rNDV/Flu/SIV-Gag boost combination in mice"	Two members were chosen to review the protocol. The protocol needs to be evaluated before the next meeting.	If the proposal is approved, a letter will be sent stating a satisfactory evaluation.

TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>The following proposals are still pending for approval:</p> <p>Dr. Irma L. Febo, "PACTG P1059"</p> <p>Dr. Annabell Segarra, "Estrogen and cocaine sensitization in the female rat".</p> <p>Dr. Carmen Zorrilla, "HVTN Protocol 403".</p>	<p>The information requested for approval was presented.</p> <p>Dr. Zorrilla sent letter including details that were missing.</p>	<p>A letter of approval was sent.</p> <p>A letter requesting necessary information that is missing to approve her proposal was sent.</p> <p>If the information requested is complete, a letter of approval will be sent.</p>
<p>Pending matters:</p> <p>Progress on the Chemical Safety manual</p> <p>Progress on the Chemical Hygiene Plan</p> <p>Committee 'By-laws' revision</p> <p>Identify Clinical and Research laboratories. Renewal of license for the use of explosive chemicals in laboratories.</p> <p>Progress report from the Office of Safety for Research Laboratories</p>	<p>Still under revision by members of the committee.</p> <p>Still under revision by members of the committee.</p> <p>Dr. Melween Martínez requested a meeting with Dr. Lavergne to discuss the committee By-laws.</p> <p>Dr. Lavergne will follow up on the matter.</p> <p>Mr. Jossian Pagán had a meeting with the Dean of Administration. Radiation issues, Laboratory investigation and Incinerator management should be covered by the Radiation Safety office.</p>	<p>An extraordinary meeting was scheduled for October 20, 2005 to discuss the manual. Ms. Nancy Ildefonso and Ms. Vanessa Rodríguez, from CASSO office will be invited.</p> <p>Pending</p> <p>Meeting was arranged.</p> <p>Pending</p> <p>Presented and received by the committee.</p>

License for the use of Explosive Chemicals	Mr. Jossian Pagán gave a progress report. Several laboratories have presented copies of their license.	A meeting with personnel from the local police dept. will be scheduled for Investigators to participate and clarify information.
Next meeting of the Committee		November 10, 2005

TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>New matters:</p> <p>Visit from Mr. Oscar Rohena, Environmental consultant, and Mr. Luis Limas, Clean Harbors representative.</p> <p>Visit from Mrs. Nancy Ildefonso, Director of CASSO office to discuss the Chemical manual and the Chemical Hygiene plan.</p> <p>Approval of minor modifications for Dr. Carlos Sariol's protocol: "Imunization of Rhesus machaques with a dengue vaccine candidate based on a venezuelan equine encephalitis (VEE) replicon vector".</p>	<p>They gave a report of the first phase of laboratory chemical management and disposal which took place on July 25-August 2, 2005. The second phase of the project was discussed in detail.</p> <p>She presented information regarding the Chemical manual.</p> <p>The committee evaluated the modifications for the protocol. The changes are the use of biological agents to include inoculations in mice, and to add personnel.</p>	<p>Once the budget is assigned, the second phase of the chemical disposal could take place on December, 2005</p> <p>Because of the time limitation, an extraordinary meeting was scheduled to discuss the manual.</p> <p>A motion was presented and seconded to approve the modifications. A letter of approval will be sent.</p>

The meeting ended at 1:35/pm


 Julio A. Laverne, Ph. D.
 Professor and Chairperson
 Institutional Biosafety Committee

11/10/2005



COMITÉ DE BIOSEGURIDAD
BIOSAFETY COMMITTEE

UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MEDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR
OFFICE OF THE CHANCELLOR

**Institutional Biosafety Committee Extraordinary Meeting
Chemical Hygiene Plan
October 20, 2005**

Members present:

Dr. Julio Lavergne
Dr. Idali Martínez
Dr. Iraida Robledo
Dr. Joseph Bloom
Mrs. Maria Teresa Rodríguez
Mr. José A. Robles
Dr. Carlos Rodríguez
Dr. Melween Martínez
Dr. Carlos Sariol
Mr. Jossian Pagán

Guests:

Ms. Vanessa Rodriguez, CASSO office
Mrs. Damarith Díaz

Meeting started at 11:15 a.m. The Chemical Hygiene Plan was distributed in the Medical Sciences Campus by the University of Puerto Rico Central Administration office in the year 2000, according to Ms. Vanessa Rodríguez, Occupational Safety officer. The Plan was developed in order to protect employees, students and visitors from exposure to hazardous chemical substances in laboratories. The document was never posted on the Intranet. The Biosafety Committee members were assigned to revise the Chemical Hygiene Plan and it was divided by pages among them, for their revision and feedback. In order to actualize the Chemical Hygiene Plan, Ms. Rodríguez was invited to the meeting since the Occupational Health and Environmental Safety office (CASSO) is mentioned several times in the manual. Her knowledge of EPA policies (Environmental Protection Agency) and her status as an Occupational Safety officer is very helpful for the revision and correction of the manual.

The document was discussed by sections:

**Appendix D, Safety warnings and labels (page 35)
Section II. Operational proceedings**

The Occupational Safety and Health Administration (OSHA) website address should be added in this section, to find the safety and warning labels that are posted on the laboratories.

Section III. Responsibilities of the Chemical Hygiene officer (page 37)

According to OSHA, there has to be a designated Chemical Hygiene officer. At the moment the Medical Sciences Campus does not have a designated officer. It is not clear, in the absence of an officer, what measures to take. This could be verified with the Dean of Administration. It was mentioned that the Principal Investigator is responsible for the laboratory. The CHP should apply to research laboratories and teaching laboratories.

Section 14.3 under Medical Vigilance

Where it says "Employee Identification", eliminate Social Security Number.

Section 20.1 Orientation (page 18)

The orientation it's only offered to employees, this also applies for trainings. It was suggested that students should be included as well. Under OSHA regulations, students are not included. The P.I. is supposed to give students a training course before they start working in the laboratory. It was suggested that a reference note can be added, to look for the OSHA Federal Register manual, part II Department of Labor (29 CFR part 1910) where it describes the Chemical Hygiene Responsibilities.

Section 21.0 Maintenance of Registry and Documents (page 19)

It needs to be clarified which office is assigned to handle the records for follow up. They are divided between CASSO and the Radiation Safety office. The laboratory personnel should keep records of all areas that are stated in this section. The following were identified:

Spills and escapes- Radiation Safety office
MSDS-Laboratory and Radiation Safety office
Hazardous Materials inventories- Laboratory and Radiation Safety office
Manifests- Laboratory and Radiation Safety office
Maintenance and repairs of equipment-Laboratory
Incidents/accidents-Laboratory and Radiation Safety office.
Environmental evaluation results in the workplace-CASSO

It should be clarified which office is responsible for the remaining records. This will be verified.

Section 23.0 Inspections (page 20)

In this section it states that the inspections are performed each trimester. It was suggested that they should be performed twice a year instead.

Section 4.0 Responsibilities (page 7) Chemical Hygiene officer

A letter addressing the situation should be written. The issue will be further discussed.

Section 25.0 Verification of implementation (page 21)

The IBC, CASSO and the Radiation Safety office will verify that the Chemical Hygiene Plan is been followed.

Appendix B, Storage of Chemical substances

Section B Safety Standards (page 26)

Several areas stated in this section are non applicable. It will be further discussed.

At this point it was suggested that the document should be revised by Mrs. Damarith Díaz and Ms. Vanessa Rodríguez. Because of their knowledge of the matter, they can make sure which sections of the CHP can be revised and updated. There are several compliance issues that have to be taken into consideration. Mrs. Díaz will cover the explosive materials area and Ms. Rodríguez will revise the EPA regulations. After the CHP is revised, the corrections will be presented to the Biosafety Committee for a final revision and approval, in order to be posted on the Intranet.

Meeting ended at 1:12 p.m.



Julio A. Lavergne, Ph. D.
Profesor and Chairperson
Institucional Biosafety Committee

11/10/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: November 10, 2005

Next meeting: December 8, 2005

Location: Animal Resources Center

Conference room

RCM building, 10th Floor

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
Carlos Sariol, MD
Idith Ortiz, MD, MPH.
María I. Roque Espina, MT
María T. Rodríguez, MT

Members Present

Julio Lavergne, Ph. D.
José A. Robles, MPH
Joseph Bloom, Ph.D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
Idith Ortiz, MD, MPH
María T. Rodríguez, MT
Iraida Robledo, Ph. D.

Members Excused

Jossian Pagán Lisboa, MS
María Roque Espina, MT
Carlos Sariol, MD
Carlos Rodríguez, Ph. D.

Guests

Dr. Luis J. Torres-Bauzá Ph.

Meeting started at 11:38 am

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
New proposal: Dr. Margarita Irizarry, "Proteomic Analysis of the Sera of Prostate Cancer in Hispanics Patients"	Two members were chosen to review the protocol.	It will be evaluated on the next meeting.

TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>The following proposals are still pending for approval:</p> <p>Dr. Annabell Segarra, “Estrogen and cocaine sensitization in the female rat”.</p> <p>Dr. Carlos Torres, “Repair of AP sites and aging in <i>Saccharomyces Cerevisiae</i>”</p> <p>Dr. Carlos Jiménez, “NE modulation of VTa excitation in Cocaine Sensitization”</p> <p>Dr. Carmen Zorrilla, “HVTN Protocol 403”.</p>	<p>A letter requesting necessary information that is missing to approve her proposal was sent.</p> <p>Some documents are missing; however the reviewers recommended an Administrative approval.</p> <p>Some information provided is inconsistent. MSDS were not provided. The proposal is incomplete.</p> <p>The SOP’s regarding procedures were not found on file.</p>	<p>Pending</p> <p>An Administrative approval letter will be sent, conditioned that Dr. Torres provides the documents missing in the proposal.</p> <p>Protocol was not approved. A letter stating the information that is missing will be send.</p> <p>A letter was sent stating the information that is missing for approval.</p>
<p>Pending matters:</p> <p>Progress on the Chemical Safety manual</p> <p>Progress on the Chemical Hygiene Plan</p> <p>Committee ‘By-laws’ revision</p>	<p>Still under revision by members of the committee.</p> <p>Still under revision by members of the committee. There are certain regulations mentioned in the document that cannot be altered or eliminated.</p> <p>Dr. Melween Martínez met with Dr. Lavergne to discuss the committee By-laws.</p>	<p>Pending.</p> <p>It will be revised on the next meeting.</p> <p>Pending</p>

Identify Clinical and Research laboratories. Renewal of license for the use of explosive chemicals in laboratories.	Dr. Lavergne will follow up on the matter. A meeting with Mr. Irving Jiménez, Dean of Administration will be scheduled to discuss the issue.	Pending
Progress report from the Office of Safety for Research Laboratories	Mr. Jossian Pagán informed the committee members about the second phase of the chemical disposal in the MSC. Clean Harbors co. will present an annual disposal plan, to be evaluated by the Dean of Administration.	Presented and received by the committee.
License for the use of Explosive Chemicals	Personnel from the local Police department inspected several laboratories in the MSC. They informed that anybody that handles explosive chemicals requires a license.	A meeting with personnel from the local police dept. will be scheduled for Investigators to participate and clarify information.
Next meeting of the Committee		December 8, 2005
Protocol renovation request from Dr. Abraham Schwartz	The request with the proper documentation was revised.	Protocol renovation was approved. A letter will be sent to Dr. Schwartz.

TOPIC	DISCUSSION/CONCLUSION	ACTION
New matters: New IBC forms to evaluate proposals.	A set of new forms including the "Protocol review checklist" and the "Project approval request form" were distributed among the members for their revision.	They will be evaluated on the next committee meeting.

The meeting ended at 1:20 pm


Julie A. Lavergne, Ph.D.

Professor and Chairperson, Institutional Biosafety Committee

12/08/2005

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: December 8, 2005

Next meeting: February 9, 2006

Location: Animal Resources Center

Conference room

RCM building, 10th Floor

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
Carlos Sariol, MD
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
María I. Roque Espina, MT
Idith Ortiz, MD, MPH.
María I. Roque Espina, MT

Members Present

Julio Lavergne, Ph. D.
José A. Robles, MPH
Joseph Bloom, Ph.D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
María T. Rodríguez, MT
Jossian Pagán, MS
María I. Roque Espina, MT
Iraida Robledo, Ph. D.
Carlos Rodríguez, Ph. D.

Members Excused

Idith Ortiz, MD, MPH
Carlos Sariol, MD

Guests

Dr. Luis J. Torres-Bauzá Ph. D.

Meeting started at 11:31 am

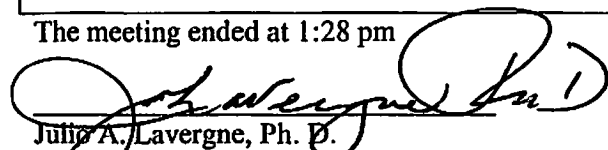
TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.

Approval of Minutes from last meeting and approval of minutes from Extraordinary Meeting/Chemical Hygiene Plan.		Both minutes were approved
New proposal: Dr. Carlos Sariol, "Study about the effects of the powder from indelible pencil on replication of the Herpes Zoster Virus".	Two members were chosen to review the protocol.	It will be evaluated on the next meeting. A letter stating that the proposal will be reviewed on the next meeting was sent to Dr. Sariol.
TOPIC	DISCUSSION/CONCLUSION	ACTION
The following proposals are still pending for approval:		
Dr. Annabell Segarra, "Estrogen and cocaine sensitization in the female rat".	Dr. Segarra sent the documentation that was missing. The evaluators still found incomplete information.	An administrative approval letter will be sent, conditioned to provision of information that is missing.
Dr. Carlos Torres, "Repair of AP sites and aging in <i>Saccharomyces Cerevisiae</i> "	Dr. Torres sent the information that was missing.	The proposal was approved by the Committee members. An approval letter will be sent to Dr. Torres.
Dr. Carlos Jiménez, "NE modulation of VTa excitation in Cocaine Sensitization"	A letter was sent stating the information that was missing for approval.	Pending.
Dr. Margarita Irizarry, "Proteomic Analysis of the Sera of Prostate Cancer in Hispanics Patients"	Some information was missing. She provided this information and it will be delivered to the evaluators.	Pending
Dr. Carmen Zorrilla, "HVTN Protocol 403".	The SOP's regarding procedures have not been provided. A follow up phone call will be made.	Pending.

Pending matters: Progress on the Chemical Safety manual	Dr. Bloom suggested that the document could be scanned. This way it is saved and it can be corrected easily.	Pending.
Progress on the Chemical Hygiene Plan	Still under revision by members of the committee. There are certain regulations mentioned in the document that cannot be altered or eliminated.	It will be revised on the next meeting.
Committee 'By-laws' revision	Dr. Melween Martínez met with Dr. Lavergne to discuss the committee By-laws. The corrections will be sent to the secretary.	Pending
Identify Clinical and Research laboratories.	Dr. Lavergne will follow up on the matter. A meeting with Mr. Irving Jiménez, Dean of Administration will be scheduled to discuss the issue.	Pending
Progress report from the Office of Safety for Research Laboratories	Dr. Lavergne informed the committee members about an annual disposal plan, developed by Clean Harbors, called Apollo to be evaluated by the Dean of Administration. The Apollo plan will also cover license renewals and laboratory trainings.	Presented and received by the committee.
License for the use of Explosive Chemicals	A meeting with personnel from the local police dept. will be scheduled for Investigators to participate and clarify information.	Pending
Next meeting of the Committee		February 9, 2006

TOPIC	DISCUSSION/CONCLUSION	ACTION
New matters: Meeting with Irving Jiménez, Dean of Administration.	The need for a Chemical officer and a Biological officer for the MSC was discussed. It was also suggested that all committees should be integrated; this will create research integrity. The creation of an office to enforce this was discussed.	Dr. Lavergne will follow up on the matter.

The meeting ended at 1:28 pm



Julio A. Lavergne, Ph. D.

Professor and Chairperson, Institutional Biosafety Committee

02/09/2006

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: February 9, 2006

Next meeting: March 16, 2006

Location: Animal Resources Center

Conference room

RCM building, 10th Floor

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idali Martínez, Ph. D.
Melween Martínez, DVM
Carlos Sariol, MD
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
María I. Roque Espina, MT
Idith Ortiz, MD, MPH.
María I. Roque Espina, MT

Members Present

Julio Lavergne, Ph. D.
José A. Robles, MPH
Joseph Bloom, Ph.D.
Carlos Rodríguez, Ph. D.
Melween Martínez, DVM
María T. Rodríguez, MT
Jossian Pagán, MS
Carlos Sariol, MD

Members Excused

Idith Ortiz, MD, MPH
Idali Martínez, Ph. D.
María I. Roque Espina, MT
Iraida Robledo, Ph. D

Guests

Dr. Luis J. Torres-Bauzá Ph. D.

Meeting started at 11:35 am

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
New proposals: Dr. Jennifer Barreto "Cellular and molecular changes associated with reproductive health after androgen exposure during puberty".	Two members were chosen as primary and secondary evaluators to revise this proposal.	It will be revised on the next meeting of the IBC.

<p>Dr. Eleanor Jiménez, PACTG P1059 “A Phase I Open Label Study to Evaluate the Safety and Tolerability of Recombinant HIV-1 vaccines in HIV-1 infected Young Adults with Control of HIV-1 Replication and on Stable High Active Antiretroviral Therapy”.</p>	<p>Since Dr. Jiménez works in the Municipal Hospital, her AD-HONOREM appointment was requested. It has not been renovated since 1994. This requires that a MSC investigator submits the protocol.</p>	<p>A letter will be sent to Dr. Jiménez explaining the required procedures, in order to evaluate her proposal.</p>
<p>Dr. Anil Kumar, “Recombinant Influenza and NDV in Monkey Model of AIDS”.</p>	<p>Two members were chosen as primary and secondary evaluators to revise this proposal.</p>	<p>It will be revised on the next meeting of the IBC.</p>
<p>Dr. Anil Kumar, “Effect of Poly-drug abuse in Macaque Model of AIDS”.</p>	<p>Two members were chosen as primary and secondary evaluators to revise this proposal.</p>	<p>It will be revised on the next meeting of the IBC.</p>
TOPIC	DISCUSSION/CONCLUSION	ACTION
<p>The following proposals are still pending for approval:</p>		
<p>Dr. Annabell Segarra, “Estrogen and cocaine sensitization in the female rat”.</p>	<p>Dr. Segarra sent the documentation that was missing. Evaluators approved the protocol.</p>	<p>An approval letter will be sent.</p>
<p>Dr. Carlos Torres, “Repair of AP sites and aging in Saccharomyces Cerevisiae”</p>	<p>Dr. Torres sent the information that was missing. The proposal was approved by the Committee members.</p>	<p>An approval letter will be sent.</p>
<p>Dr. Carlos Jiménez, “NE modulation of VTa excitation in Cocaine Sensitization”</p>	<p>Dr. Jiménez sent the information that was missing for approval.</p>	<p>The documentation will be delivered to the evaluators for their revision.</p>

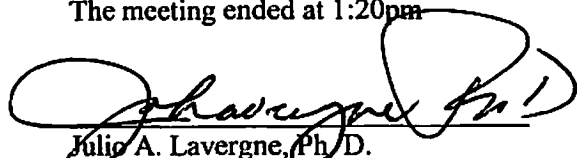
Dr. Margarita Irizarry, "Proteomic Analysis of the Sera of Prostate Cancer in Hispanics Patients"	Some information is still missing, ex. personnel training certificates and an accurate list of chemicals.	An Administrative Approval letter will be sent conditioned to provide the missing information.
Dr. Carmen Zorrilla, "HVTN Protocol 403" .	The SOP's regarding procedures have not been provided.	Pending.
Dr. Carlos Sariol, "Study about the effects of the powder from indelible pencil on replication of the Herpes Zoster Virus" .	The evaluators approved the protocol.	An Approval letter will be sent.
Dr. Ana Espino, "Immune Response in Mice Alter Vaccination with a novel F. Hepatica vaccine" .	Some information is missing, ex. personnel training certificates, detailed safety procedures.	An Administrative Approval letter will be sent, conditioned to provide the missing information.
Dr. José Rodríguez Medina, "Genetic and Proteomic Analysis of Myosin II-dependent Endosome Transport" .	SOP's, personnel training certificates and additional information is missing.	A non-approval letter will be sent, stating all information required for the proposal's approval.
Dra. Carmen Cadilla, "High -level Production of Recombinant Wild Type and mutant Sulfidereactive Hemoglobin I (Hbl) from Lucina pectinata in E. coli" .	Some information is still missing, ex. personnel training certificates.	An Administrative Approval letter will be sent, conditioned to provide the missing information.

Dr. Idali Martínez, “ Characterization of the Immune Response and Outcome of Sequential Flavivirus infections in the mouse model ”.	Some information is missing, ex. personnel evidence of training for BSL2 and BSL3, detailed description for experimental procedures and methodology.	An Administrative Approval letter will be sent, conditioned to provide the missing information.
Dr. Carlos Rodríguez, “ Arsenic Exposure from Fish Consumption in Vieques ”	Some information is missing, ex. description of safety handling and shipping of urine samples and personnel training certificates.	An Administrative Approval letter will be sent, conditioned to provide the missing information.
Dr. Carlos Rodríguez, “ Metales Pesados en Sedimentos y Animales Acuáticos del Estuario de la Bahía del Tablazo de Venezuela y de la Reserva Natural de Humacao, Puerto Rico ”.	Personnel training certificates are missing.	An Administrative Approval letter will be sent, conditioned to provide the missing information.
The following renewal requests were approved:		
Dr. Idali Martínez, “ Evaluation Studies of Bicistronic Dengue-4 DNA Vaccine ” and “ Evaluation Studies of a Dengue-2 DNA Vaccine in Monkeys ”.	Only personnel changes were notified.	Renewal letters for both proposals were sent.
Dr. María Sosa, “ Crustacean Aminegeric Gene Expression as a function of Dominance Status ” and “ Crustacean Amine Receptors and Agresion in the Prawn (3240104) ”	Only personnel changes were notified. Updated training certificates were provided	Renewal letters for both proposals were sent.
Dr. Loyda Meléndez, “ Protein Profiling of ”	Only personnel changes were notified.	Renewal letters for both proposals were sent.

<p>Putative Antiretroviral Factors in Placental Macrophages” and “Monocyte Immunity and HIV Dementia”</p> <p>Pending matters: Progress on the Chemical Safety manual</p> <p>Progress on the Chemical Hygiene Plan</p> <p>Committee ‘By-laws’ revision</p> <p>Identify Clinical and Research laboratories.</p> <p>Progress report from the Office of Safety for Research Laboratories</p> <p>License for the use of Explosive Chemicals</p> <p>Next meeting of the Committee</p>	<p>Updated training certificates were provided</p>	<p>Pending.</p> <p>Pending</p> <p>Pending</p> <p>Pending</p> <p>Presented and received by the committee.</p> <p>Pending</p> <p>April , 2006</p>
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New matters: Visit from the Dean of Administration, Mr. Irving Jiménez .	Mr. Jiménez gave a briefing about the Environmental Protection Agency (EPA) visit to the MSC. The Apollo project is under evaluation.	Received by the IBC.
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The meeting ended at 1:20pm



Julio A. Lavergne, Ph.D.

Professor and Chairperson, Institutional Biosafety Committee

03/16/2006

Minutes of the RCM/UPR BIOSAFETY COMMITTEE

Chairperson: Julio A. Lavergne, Ph. D.

Date: March 16, 2006

Next meeting: April 20, 2006

Location: Chancellor's Conference room

RCM building, 7th Floor

Time: 11:00 a.m.-1:00 p.m.

Members

Julio Lavergne, Ph. D.
Jossian Pagán Lisboa, MS
Iraida Robledo, Ph. D.
Joseph Bloom, Ph. D.
Idalí Martínez, Ph. D.
Melween Martínez, DVM
Carlos Sariol, MD
José A. Robles, MPH
Carlos Rodríguez, Ph. D.
María I. Roque Espina, MT
Idith Ortiz, MD, MPH.
María I. Roque Espina, MT

Members Present

Julio Lavergne, Ph. D.
José A. Robles, MPH
Joseph Bloom, Ph.D.
María I. Roque Espina, MT
Melween Martínez, DVM
María T. Rodríguez, MT
Jossian Pagán, MS
Carlos Sariol, MD
Idith Ortiz, MD, MPH
Idalí Martínez, Ph. D.
María I. Roque Espina, MT

Members Excused

Carlos Rodríguez, Ph. D.

Guests

Dr. Luis J. Torres-Bauzá Ph. D.

Meeting started at 11:38 am

TOPIC	DISCUSSION/CONCLUSION	ACTION
Verification of quorum		Quorum was established.
Approval of Minutes from last meeting		Approved
New proposals: Dr. Melween Martínez, "Evaluation of HIV Vaccines".	Two committee members were chosen to revise this proposal.	It will be evaluated on the next meeting of the IBC.

*Dr. Edna Mora, "IL-3R and Estradiol in the Development of bone metastases in a Breast Cancer model".	Two committee members were chosen to revise this proposal.	It will be evaluated on the next meeting of the IBC.
TOPIC	DISCUSSION/CONCLUSION	ACTION
The following proposals are still pending for approval:		
Dr. Anil Kumar, "Recombinant Influenza and NDV in Monkey Model of AIDS".	Dr. Kumar needs to submit new SOP's, clarify in detail safety procedures, waste handling and disposal.	A Non-approval letter will be sent requesting the information that is missing.
Dr. Anil Kumar, "Effect of Poly-drug abuse in Macaque Model of AIDS".	The investigation for this proposal will take place in Ponce, P.R. All documentation required was submitted.	An Approval letter will be sent.
Dr. Margarita Irizarry, "Proteomic Analysis of the Sera of Prostate Cancer in Hispanics Patients"	Dr. Irizarry provided the documentation that was missing.	An Approval letter will be sent.
Dr. Carmen Zorrilla, "HVTN Protocol 403".	Dr. Zorrilla has not provided the information requested for approval of her protocol.	Pending
Dr. Ana Espino, "Immune Response in Mice Alter Vaccination with a novel F. Hepatica vaccine".	Dr. Espino provided the documentation that was missing.	An Approval letter will be sent.
Dra. Carmen Cadilla, "High -level Production of Recombinant Wild Type and mutant Sulfidereactive Hemoglobin I (Hbl) from Lucina pectinata in E. coli".	Dr. Cadilla sent documentation that was missing.	An Approval letter will be sent.

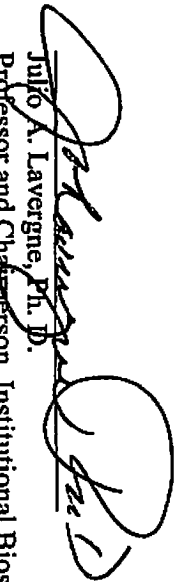
Dr. Idali Martínez, “ Characterization of the Immune Response and Outcome of Sequential Flavivirus infections in the mouse model ”.	An Administrative Approval letter was sent, conditioned to provide some missing information. Dr. Martinez provided the documentation requested by the committee.	An Approval letter will be sent.
Dr. Carlos Rodríguez, “ Arsenic Exposure from Fish Consumption in Vieques ”	Dr. Rodríguez provided the documentation that was missing.	An Approval letter will be sent.
Dr. Carlos Rodríguez, “ Metales Pesados en Sedimentos y Animales Acuáticos del Estuario de la Bahía del Tablazo de Venezuela y de la Reserva Natural de Humacao, Puerto Rico ”.	Dr. Rodríguez provided the documentation that was missing.	An Approval letter will be sent.
Dr. Jennifer Barreto, “ Cellular and Molecular changes associated with reproductive health after Androgen exposure during puberty ”.	Dr. Barreto needs to submit a list of chemicals used in the protocol.	An Administrative approval letter will be sent, conditioned to provide the information that is missing.
Dr. Eleanor Jiménez, “ PACTG P1059 ”.	Dr. Jiménez provided the documentation that was missing.	An Approval letter will be sent.
Pending matters: Progress on the Chemical Safety manual and the Chemical Hygiene Plan	Both manuals are under revision. An extraordinary meeting will be scheduled to finish the corrections. In the meantime, copies of the current manuals will be posted on the intranet until the final revision is approved.	The Extraordinary Meeting was scheduled for March 30, 2006.

IBC 'By-laws' revision	Dr. Melween Martinez revised and made several corrections to the Committee 'By-laws'.	The revision was discussed. Final approval is pending.
Progress report from the Office of Safety for Research Laboratories	Mr. Jossian Pagán announced the beginning of the 2 nd phase of the Chemical disposal in laboratories, by Clean Harbors.(March 13-23, 2006). The Apollo Project was approved by the Dean of Administration.	Received by Committee.
License for the use of Explosive Chemicals	Damarith Díaz, from the Radiation Safety office will schedule a meeting with the Police department.	Pending
IBC revision of proposal evaluation forms.	The forms will be revised on the IBC Extraordinary meeting.	The Extraordinary Meeting was scheduled for March 30, 2006.
Next meeting of the Committee.		April 20 , 2006

New matters:		
Mrs. Damarith Díaz is organizing a presentation with personnel of the Fisher Company, about safety equipment, specifically eyewash models and portable showers for laboratories.		Presentation date will be announced.

*Dr. Edna Mora's proposal was reviewed in advance. It was approved and a letter was sent on March 30, 2006.

The meeting ended at 1:25pm



Julio A. Laverne, Ph. D.
Professor and Chairperson, Institutional Biosafety Committee

04/20/2006