Tulane University

Laura S. Levy, PhD
Associate Senior Vice President for Research

April 25, 2006

Edward H. Hammond
Director
The Sunshine Project
PO Box 41987
Austin, Texas 78704

Dear Mr. Hammond:

Enclosed are the materials responsive to your request.

Sincerely,

Laura S. Levy

Laura S. Levy, Ph.D
Associate Senior Vice President
for Research
Institutional Official for the IBC

LSL/jtj
Enclosures

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Tulane University
Institutional Biosafety Committee

Meeting Minutes
November 10, 2004

A meeting of the Tulane University Institutional Biosafety Committee (IBC) was held on the date set forth above, at approximately 1:15 p.m., in room 504 of the J. Bennett Johnston Health and Environmental Research Building.

The following members of the IBC were in attendance:

Robert F. Garry, IBC Chair (Microbiology/Immunology)
Mouhamed Awayda (Physiology)
James L. Blanchard (Tulane National Primate Research Center – Veterinary Medicine)
John D. Clements (Microbiology/Immunology)
Gary W. Hoyle (Medicine – Pulmonary Diseases)
Debra W. Jackson (Environmental Health and Safety)
Laura S. Levy (Microbiology/Immunology) (ex-officio member)
David A. Mullin (Cell and Molecular Biology)
Nazih L. Nakhoul (Medicine – Nephrology)
Cheryl A. Nickerson (Microbiology/Immunology)
Michael J. Schurr (Microbiology/Immunology)
Vicki Traina-Dorge (Tulane National Primate Research Center – Microbiology)
Weiping Zou (Medicine – Hematology/Oncology)

The following persons attended the meeting as invited guests:

Kathleen M. Kozar, Director, Office of Research Administration
Michael B. Gebhardt, Associate General Counsel (by teleconference)

The Chair called the meeting to order at 1:15 p.m.

I. Introduction

The Chair related the sincere appreciation of Paul Whelton, Senior Vice President for Health Sciences, to the IBC members for their service to the University.

II. Associate Senior Vice President for Research

The Chair introduced Prof. Laura S. Levy, recently appointed to the position of Associate Senior Vice President for Research.

Levy described the function of her new position and explained that the IBC will report to her office going forward. Levy indicated an intent to have regular meetings with the IBC Chair, that a staff member will be hired or assigned to perform administrative and record-

keeping functions for the IBC, and that the Office of Environmental Health and Safety (OEHS) will assist principal investigators in providing the IBC with fully-developed biosafety determinations for individual research projects.

Jackson described the OEHS' plans to conduct regular inspection and certification of University laboratories as to biosafety practices and procedures.

III. Correspondence with NIH OBA

Kozar described the activities of the Sunshine Project, the letter received from NIH OBA, and the activities underway in connection with the University's response.

The Chair briefly described the history and background of the NIH Guidelines for Research Involving Recombinant DNA Molecules. The Chair described the scope of the NIH Guidelines, a copy of which was provided to each person in attendance at the meeting. The Chair described the role and responsibilities of the IBC. Discussion ensued regarding the obligations of principal investigators in making initial determinations. It was suggested that additional training be provided to principal investigators regarding these obligations and the NIH Guidelines in general. It was asked whether the IBC should have a member with expertise in plant research. It was generally agreed that the need for such expertise is rare, and it can be obtained by the IBC on an ad-hoc basis.

IV. Review of Research Project Approval Procedures

The Chair described the process by which research projects are submitted for IBC review and/or approval. A description of the process was provided to each person in attendance at the meeting. Discussion ensued regarding possible revisions to the University's internal routing form for purposes of adding additional detail, and archiving of reviewed protocols. Further discussion ensued regarding the development of an electronic routing process.

V. Proposed Revision of IBC Policies and Procedures

The Chair described the expanded responsibility of IBCs in general in light of Federal biosecurity initiatives and concerns regarding "dual-use" research or certain research involving infectious agents. The Chair described efforts underway by a working group consisting of senior administrators of the Tulane University Health Sciences Center, OEHS, and members of the IBC to draft revised policies and procedures for the IBC to provide the IBC and OEHS with additional infrastructure and standardized processes for the review of any research project raising biosafety concerns.

Balsamo discussed the establishment of the position of biological safety manager, as well as biological safety officers in each department, and the responsibilities associated with these positions.

The Chair stated that updates will be provided to and input solicited from the IBC from time to time regarding the status of the revised policies and procedures.

VI. Adjournment

There being no further business to be conducted, the meeting was adjourned at approximately 2:45 p.m.

Faithfully submitted,

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Prof. Robert F. Garry, Chair

Tulane University
Institutional Biosafety Committee
3-4-05

The meeting was called to order at 1 pm on March 4, 2005.

Present: Garry, Balsamo, Blanchard, Mullin, Clements, Schurr, Nickerson, Awayda, Nakhoul, Hoyle, Traina-Dorge, Jackson

Absent: Zou, El-Dahr, Anderson, Campagna

Two old protocols were discussed and approved as described in the attached Table. Nine new protocols we discussed. One was determined to be not applicable. Four protocols were approved and four were deferred for additional information.

A productive discussion regarding the consolidation of TNPRC and TMC review ensued. It was agreed to combine the best features of each form into a single document.

A brief discussion about the review of the Biosafety Manual was conducted. The committee agreed to review the current draft prior to the next IBC meeting.

The meeting was adjourned at 2:25 pm.

Tulane University
Institutional Biosafety Committee
3-4-05

Old Business:

Protocol #	Title	PI	Action
1	SL3-3 Pathogenesis as a Model for Premalignancy"	Laura S. Levy, Ph.D.	approved
2	Altering mesencymal stem cells to enhance cardiac repair.	Yao-Hua Song, Ph.D.	approved

New Business:

Protocol #	Title	PI	Action
A224	West Nile Vaccine for Non-human Primates	Marx, PhD, Preston	not applicable
A2843-C	Analysis of EBNA1 siRNAs for Inhibiting NPC Tumor Growth	Flemington, Erik	approved
A 2875	Mouse mammary tumor virus melatonin transgenic	Steve Hill	approved
A2844-C	Development of EBNA1 si RNAs as potential therapeutics	Quinyan Yin	approved
A2880-D	TGF-Beta in Interstital Lung Disease	Brody, Ph.D., Arnold R	deferred
A233	Repopulation of Macaque Lungs with Macaque Mesenchymal Stem Cells	Weiss, MD, PhD, Daniel J.	approved
A234	RNA Interference for Flaviviral Encephalitis	Swamy, MD, Manjunath	deferred
A0302	Roles of hippocampal/neostriatal systems in multiple forms of memory	Paul Colombo, Ph.D.	deferred
3	Pathogenicity of M. tuberculosis mutants in macaques	Andrew Lackner, Ph.D.	deferred

Homework:

A2899	Stem Cell Therapy for Pulmonary Hypertension	Phil Kadowitz, Ph..D.

Tulane University
Institutional Biosafety Committee

Meeting Minutes
May 17, 2005

A meeting of the Tulane University Institutional Biosafety Committee (IBC) was held on the date set forth above, in room 504 of the J. Bennett Johnston Health and Environmental Research Building.

The following members of the IBC were in attendance:

John D. Clements, IBC Chair (Microbiology/Immunology)
Judy Anderson (Community Representative)
James Balsamo (Office of Environmental Health & Safety)
Jane El-Dahr (Pediatrics – Allergy – Immunology)
Robert F. Garry (Microbiology/Immunology)
Gary W. Hoyle (Medicine – Pulmonary Diseases)
Debra W. Jackson (Environmental Health and Safety)
David A. Mullin (Cell and Molecular Biology)
Nazih L. Nakhoul (Medicine – Nephrology)
Cheryl A. Nickerson (Microbiology/Immunology)
Michael J. Schurr (Microbiology/Immunology)
Weiping Zou (Medicine – Hematology – Oncology)

The following persons attended the meeting as invited guests:

Sheila Garrison, Chair, Institutional Animal Use and Care Committee (IACUC)
Helen Kitzman, Staff Member, Center for Bioenvironmental Research
Michael Gebhardt, Associate General Counsel

The Chair called the meeting to order at approximately 2:00 p.m.

I. Introduction

Dr. Clements introduced himself, noting that he recently accepted the position of IBC Chair. Dr. Clements thanked Dr. Garry, outgoing IBC Chair for his service to the IBC and the University.

Dr. Clements then described the increased focus by the NIH on the activities of institutional biosafety committees, and the need to continuously review and update IBC policies and procedures to be consistent with federal regulations.

II. Discussion of IBC Policies and Procedures

Dr. Clements described the new Tulane IBC Policy Manual for the use of Recombinant DNA. Dr. Clements explained that the policy manual is based heavily on the NIH's *NIH Guidelines for Research Involving Recombinant DNA Molecules*, and was created in consultation with the Associate Senior Vice President for Research and University Research Compliance Officer, with the intent of providing Principal Investigators with clear guidance as to their responsibilities with respect to applicable research projects.

Dr. Clements noted that it is the responsibility of Principal Investigators to become familiar with the *NIH Guidelines* and Tulane's IBC policy manual. Dr. Clements also noted that several forms had also been created to better organize the process of applying for IBC approval and registering recombinant DNA research on an annual basis.

Discussion ensued regarding the policy manual and forms. After discussion, Dr. Clements agreed to discuss modifications to the manual and forms with Laura Levy, Associate Senior Vice President for Research, to permit initiation of certain classes of recombinant DNA research with simultaneous submission of the *Application for Non-Exempt Use of Recombinant DNA Molecules* as specified in section III-E of the *NIH Guidelines*.

Discussion ensued regarding the timing of applications for IBC approval relative to the submission of grant applications. It was generally agreed that because IBC approval in most cases is not a prerequisite to a grant application but is necessary for the conduct of the research, that application for IBC approval should be regarded as ongoing and not linked to grant submission. The need to coordinate the approval process with IACUC was discussed.

III. Approval of Minutes from Previous Meeting

Dr. Clements requested that IBC members review the draft minutes from the March 4, 2005 meeting of the IBC and provide comments, if any. After review, no comments were forthcoming.

Upon a motion duly made and seconded, the minutes were unanimously approved.

IV. Review Status of Protocols

Dr. Clements initiated discussion regarding the status of the various protocols set forth on Exhibit A hereto. It was generally agreed that IBC consideration of certain protocols referred to it by IACUC should be deferred pending submission by the Principal Investigators to the IBC of the new *Application for Non-Exempt Use of Recombinant DNA Molecules*. Upon a motion duly made and seconded, the decision to defer review was unanimously approved.

Dr. Clements stated that the following principal investigators would be notified by e-mail: Hill (0503008); Yin (0503009); Weiss/Bohm (0504013); Flemington (0504021); Colombo (0503010); Swamy/Ratterree (0504020); Brody (0504022); Kadowitz

(0503012); Marx (0504015); Kuroda (0504014); Godbey (0504016); Dash (0504017); Morris (0504018); Hellstrom (0504025).

Dr. Clements initiated discussion regarding a requested change in the name of a protocol (Levy (0503006)). After discussion, upon a motion duly made and seconded, the name change was unanimously approved.

Dr. Clements initiated discussion regarding a protocol (Lackner (0503011)). It was agreed that the protocol requires BSL-3 level containment due to use of M. tuberculosis, SIV and SHIV as specified in Section III-D-1-b of the *NIH Gudelines*. Dr. Balsamo confirmed that a BSL-3 facility was functioning and available for the conduct of the protocol. Upon a motion duly made and seconded, the conduct of the protocol was unanimously approved.

Dr. Clements stated that he will provide signed approval letters to the following principal investigators for protocols previously approved by the IBC: Levy (0503006) and Song (0503007) and for the Lackner (0503011) protocol approved at this meeting.

V. Procedures for Review of Protocols; Future Meeting Dates

Dr. Clements initiated discussion regarding the IBC's procedures for distributing and reviewing protocols. Discussion ensued regarding whether IBC members would prefer to receive protocols electronically or in hard copy. It was generally agreed that all protocols would be distributed to all members electronically, and that any members desiring hard copies could either print from email or request hard copies from the IBC office.

Dr. Clements further noted that although all protocols would be distributed to all members, his intent was to assign each protocol to specific IBC member, which member would then be responsible for presenting the protocol for discussion at an IBC meeting.

Dr. Clements then proposed that a regular meeting schedule be established, and suggested the third Monday of each month at 12 noon, for approximately two hours.

VI. Adjournment

There being no further business to be conducted, the meeting was adjourned at approximately 4 p.m.

Faithfully submitted,

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John Clements, Chair

Exhibit A

Tulane University
Institutional Biosafety Committee - 5-17-05
Protocols for Discussion

Protocol #	Title	PI	Action
0501001	Biophysical properties of a cloned tetrodotoxin-resistant sodium channel (mNav1.8)	Geoffrey Schofield	None Required
0501002	The role of telomeric repair proteins in cancer	Arthur Lustig	None Required
0502003	LL-37 is overexpressed and secreted by ovarian tumors resulting in the recruitment of mesenchymal stem cells and induction of angiogenesis	Aline Scandurro	None Required
0503004	Pseudomonas aeruginosa virulence factors required for pulmonary infection	Michael Schurr	None Required
0503005	Substance P and NK-1R antagonists in simian AIDS, subgrant of Neurokinin-iR (SP receptor) antagonists for HIV therapy	Andrew Lackner	None Required
0503006	MuLV Pathogenesis as a Model for Premalignancy	Laura S. Levy	Name Change
0503007	Altering mesenchymal stem cells to enhance cardiac repair	Yao-Hua Song	None Required
0503008/A2875	Mouse mammary tumor virus melatonin transgenic	Steve Hill	Deferred
0503009/A2844	Development of EBNA1 si RNAs as potential therapeutics	Quinyan Yin	Deferred
0504013/A233	Re-population of Macaque Lungs with Macaque Mesenchymal Stem Cells	Daniel Weiss	Deferred
0504021/A2843	Analysis of EBNA1 siRNAs for inhibiting NPC tumor growth	Erik Flemington	Deferred
0503010/A0302	Roles of hippocampal/neostriatal systems in multiple forms of memory	Paul Colombo	Deferred
0503011	Pathogenicity of M. tuberculosis mutants in macaques	Andrew Lackner	Approved
0504020/A234	RNA interference for Flaviviral encephalitis	Manjunath Swamy	Deferred
0504022/A2880	TGF-beta in Interstitial Lung Disease	Arnold Brody	Deferred
0503012/A2899	Stem Cell Therapy for Pulmonary Hypertension	Phil Kadowitz	Deferred
0504015/A224	West Nile Vaccine for Non-human Primates	Preston Marx	Deferred
0504014/A241	Role of dendritic cells for effective AIDS vaccine	Marcelo Kuroda	Deferred

0504016/A0307	Transfection via Food Bourne Vectors, Pilot Study	WT Godbey	Deferred
0504017/A2900	Effect of interferon and SiRNA on HCV gene expression in mouse model	Srikanta Dash	Deferred
0504018/A2901	Altered fibrogenesis in mutant p53-expressing mice	Gilbert Morris	Deferred
0504019/A2904	Kidney-specific p53 transgenic mice	Samir El-Dahr	Deferred
0504023/A246	Generation Of Monospecific Polyclonal Immune Serum In Rabbits	Mario Philipp	N/A – No rDNA
0504024/A2886	Therapeutic Potential of PACAP in Multiple Myeloma	Min Li	N/A – No rDNA
0504025/A2892	Hepatocyte Growth Factor (Hgf) And Insulin Growth Factor -1 (Igf-1) Modified Mesenchymal Stem Cells For Therapy Of Diabetes- Induced Erectile Dysfunction In Rats	Wayne Hellstrom	Deferred

Tulane University
Institutional Biosafety Committee

Meeting Minutes
June 20, 2005

A meeting of the Tulane University Institutional Biosafety Committee (IBC) was held on the date set forth above, in room 504 of the J. Bennett Johnston Health and Environmental Research Building.

The following members of the IBC were in attendance:

John D. Clements, IBC Chair (Microbiology/Immunology)
James Balsamo (Office of Environmental Health & Safety)
James L. Blanchard (Tulane National Primate Research Center – Veterinary Medicine)
Angelique Dorsey (Ex-Officio, University Research Compliance Officer)
Robert F. Garry (Microbiology/Immunology)
Gary W. Hoyle (Medicine – Pulmonary Diseases)
Debra W. Jackson (Environmental Health and Safety)
David A. Mullin (Cell and Molecular Biology)
Nazih L. Nakhoul (Medicine – Nephrology)
Michael J. Schurr (Microbiology/Immunology)
Weiping Zou (Medicine – Hematology – Oncology)

The following persons attended the meeting as invited guests:

Thomas Voss (Microbiology and Immunology)
Bruce Bunnell (Gene Therapy)

The chair called the meeting to order at approximately 12:10 p.m.

I. Introduction

Dr. Clements announced that Drs. Bunnel and Voss are guests today because Dr. Clements is requesting that they be appointed as full members to the committee.

Dr. Clements initiated discussion regarding the appropriate procedure for reviewing protocols when an IBC committee member is the principal investigator or is otherwise involved substantially with the study. One suggestion was to allow the committee member to participate in the discussion, but recluse him- or herself from voting. Another was that the member would not participate in the discussion of the protocol and would leave the room from the beginning of the review until after voting had ended. The committee decided to allow members to stay during protocol review to answer questions and to leave prior to discussion and voting.

II. Approval of Minutes from Previous Meeting

Dr. Clements requested that IBC members review the draft minutes from the May 17, 2005 meeting of the IBC and provide comments, if any. With no comments or changes received, the minutes were unanimously approved upon a duly made motion and proper second.

Regarding the March 4, 2005 meeting minutes, there was a motion to modify. This motion was properly moved, seconded, and unanimously approved.

III. Old Business

IBC policy manual: The Tulane University IBC policy manual previously did not have a provision for review of research simultaneous with initiation of the study. Since the National Institutes of Health allows such submissions, the Tulane IBC policy manual has been changed to reflect this review status.

Annual registrations: Reported that the IBC has received 17 annual registrations from researchers in anticipation of the June 30, 2005 deadline.

IV. Protocol Review

1. **#0504013, Daniel Weiss, "Repopulation of Macaque Lungs with Macaque Mesenchymal Stem Cells"**

   Dr. Bunnell stated that he has a conflict of interest in this protocol. Dr. Clements asked that he stay during the review due to his expertise, but to leave during the discussion and vote. Discussion ensued regarding the reason PI listed this protocol as falling into risk group III. There was a determination that there should not be any replication-competent HIV virus in this protocol.

   After Dr. Bunnell left the room, the protocol was unanimously approved after a proper motion and second. In accordance with Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the appropriate bio-containment level for the research described in this proposal is BSL-2 or BSL-2N.

2. **#0504016, W T Godbey, "Transfection via Food Bourne Vectors, Pilot Study"**

   Overall, the committee felt that inadequate information was provided for this protocol to be evaluated and noted that the PI failed to answer the required questions. In addition, a number of specific points were raised which should be addressed. Specifically, the DNA was specified to be a mammalian plasmid, but no information was provided regarding the nature of that plasmid and any potential for animal to animal transfer, integration, or potential human risks. The

strain of mice to be used should be indicated. There was no indication of adequate training of personnel. The application was deferred pending clarification by the PI.

3. **#0504017, Srikanta Dash, "Effect of interferon and SiRNA on HCV gene expression in mouse model"**

   Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the appropriate bio-containment level for the research described in this proposal is BSL-2 or BSL-2N.

4. **#0504021, Erik Flemington, "Analysis of EBNA1 siRNAs for inhibiting NPC tumor growth"**

   The protocol was unanimously approved, after proper motion and second. In accordance with Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the appropriate bio-containment level for the research described in your proposal is BSL-2 or BSL-2N.

5. **#0504022, Arnold Brody, "TGF-beta in Interstitial Lung Disease"**

   See discussion notes for protocol #0506034 by Morris.

6. **#0505026, Jeremy Stark, "Mammalian DNA Repair"**

   The committee required clarification on a number of items before this application can be considered for approval.

   1. A better description of the plasmid DNA should be provided (Bluescript is a prokaryotic expression plasmid). In this proposal, antibiotic resistance is being transferred to ES and 293 cells under control of the pgk promoter (which is not found in Bluescript) with no additional DNA inserts. The committee needs to know exactly which plasmid vectors will be employed and which, if any, genetic sequences will be inserted into those vectors.

   2. Information should be provided as to what will be done with the cells after they are transfected (in vitro studies or reintroduction into mice?).

   3. Clarification should be provided regarding the intention to express diphtheria toxin since, in accordance with section III-B of the *NIH Guideline*, this would require prior approval of NIH/OBA. If this is the PI's intent, he should also provide information regarding the source, manipulation, and what special precautions he proposes to observe.

4. More information on the proposed use of retroviral vectors should be provided and which proteins will be expressed.

The protocol was deferred pending clarification by the PI.

7. **#0505027, Elizabeth Didier, "Cloning and expression of microsporidial drug targets"**

Following presentation, the protocol was unanimously approved upon proper motion and second. In accordance with Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the appropriate bio-containment level for the research described in this proposal is BSL-2.

8. **#0506032, Vicki Taina-Dorge, "Animal Models for Improved VZV Vaccines"**

Following presentation, the protocol was unanimously approved upon proper motion and second. In accordance with Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the appropriate bio-containment level for the research described in this proposal is BSL-2.

9. **#0506033, Diane Blake, "Selection of high-affinity synergistic antibodies from a phage-display library"**

In accordance with Section III-F of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the proposed research is Exempt from the *NIH Guidelines* and registration of this specific project with the Institutional Biosafety Committee is not required.

10. **#0506034, Gilbert Morris, "Altered fibrogenesis in mutant p53-expressing mice"**

This protocol was reviewed in tandem with protocol #0504022 by Brody because they are essentially the same. Committee discussed whether Brody's intended use of face masks as a safety precaution was accurate since a full-face mask requires pulmonary function tests and proper fitting. The IBC thought the safety measures as proposed by Morris were appropriate because he was conducting the research under a hood. Upon proper motion and second, the committee unanimously approved the protocol as proposed by Morris. Brody's protocol was approved pending clarification regarding the need for using full face masks. In accordance with Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the appropriate bio-containment level for the research described in your proposal is BSL-2 or BSL-2N.

V. <u>New Business</u>

Website: Dr. Clements announced the launch of the IBC website at www.ibc.tulane.edu.

Infectious agents review: Dr. Clements stated that procedures for reviewing protocols utilizing infectious agents need to be developed by the committee. The target date for development and dissemination of Tulane's guidelines is three months. The website will be updated and revised once the procedures have been established.

IACUC issues: For protocols referred from IACUC for IBC review, Dr. Clements has notified the PIs that they need to submit an application for approval to the IBC. Also, IACUC will be sent copies of the decision letters for IBC protocols involving the use of animals. Also, the PI will be instructed to notify the vivarium of the BSL level assigned and waste containment procedures prescribed by the IBC.

Laboratory certifications: Discussed when certifications of PI laboratories should occur. The committee decided that it is the PI's responsibility to conduct research in a laboratory that is certified at the level the IBC assigns.

Community representative: Dr. Clements asked members to nominate persons to serve on the committee as the community representative. He stressed the federal requirement for such a member.

VI. Adjournment

The meeting was adjourned at approximately 2 p.m.

Faithfully submitted,

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John Clements, Ph.D., Chair

Tulane University
Institutional Biosafety Committee

Meeting Minutes
July 18, 2005

A meeting of the Tulane University Institutional Biosafety Committee (IBC was held on the date set forth above, in room 504 of the J. Bennett Johnston Health and Environmental Research Building.

The following members of the IBC were in attendance:

John D. Clements, IBC Chair Microbiology/Immunology
Judy Anderson – Community Representative
James Blanchard – Tulane National Primate Research Center – Veterinary Medicine
Bruce Bunnell – Gene Therapy
Robert Garry – Microbiology/Immunology
Gary Hole – Medicine – Pulmonary Diseases
Debra Jackson – Environmental Health and Safety
David Mullins – Cell and Molecular Biology
Nazih Nakhoul – Medicine – Nephrology
Cheryl Nickerson – Microbiology/Immunology
Michael Schurr – Microbiology/Immunology
Vicki Traina-Dorge – Tulane National Primate Research Center – Microbiology
Tom Voss – Microbiology/Immunology
Weiping, Zou – Medicine-Hematology-Oncology
Angelique Dorsey (ex-officio) – University Research Compliance Officer

The chair called the meeting to order at approximately 12:05 p.m.

I. Introduction

Dr. Clements announced that he has placed in the approval letters a requirement that PI's are responsible for contacting OEHS to ensure the lab to be used for the study has been certified at the proper level.

II. Approval of Minutes from Previous Meeting

Dr. Clements requested that IBC members review the draft minutes from the June 20, 2005 meeting of the IBC and provide comments, if any. With no comments or changes received, the minutes were unanimously approved upon a duly made motion and proper second.

III. Old Business

IACUC Interface
IACUC usually sends over protocols when IACUC has a concern about animal handlers' safety. IACUC and the IBC need to develop procedures for interacting with each other. The IBC is currently asking the PI to send over IBC protocol once notified by IACUC. This will become a greater issue in reviewing infectious agents.

IV. Protocols Review

1. **#0505023, Stark, Jeremy "Mammalian DNA Repair"**

   Jeremy Start submitted a clarification of his protocol as requested by the IBC at the June meeting. Dr. Clements is satisfied with this protocol not using Diphtheria toxin. He intends to use a sub unit gene. Upon proper motion and second the committee unanimously approved the protocol.

2. **#0506030, Bunnell, Bruce "Development of in utero gene therapy procedures"**

   One reviewer indicated that he is confused by the protocol. The committee was unsure whether AAB is going to be used. Dr. Bunnell stated that AAB viruses will be used in his lab. The main risk of using the virus will be: 1) associated mutations and 2) handlers can become infected if struck or improperly contaminated. Bunnell lists BSL-2 as the safety level but the reviewer thinks BSL3 safety precautions are required.

   Handler training is an issue. The protocol states handlers will have completed institutional training, but no such training exists. Dr. Clements expressed discomfort with Bruce being in the room at this point in the discussion. Point made by one member is that having the PI's in the room gives him/her an unfair advantage because he/she is here and other PI's who are not on the committee is not. The committee agreed that even PI's on the committee will still be required to reduce response in writing. Bruce steps out of room for remainder of discussion.

   The main focus of the discussion is the appropriate containment level. Risk group 3, BSL2 is the usual classification of HIV when handling cultures. Bob Garry stated HIV has always been treated at BSL-2 or 2+ in research at Tulane. HIV can only replicate once. The committee determined that Tyvek, face shields, BSL – 2 hoods and building and room numbers are needed. There was a motion for approval at BSL-2 levels, contingent on identification of building, room numbers and clarification on training of staff. BSL-2 for animal handling is required. Approved unanimously after proper motion and second. Bruce returned following vote.

3. **#0506042, Robert, Gary, "Role of Spiroplasm in Transmissible Spongiform Encephalopathies"**

   The reviewer has some concern about the proposed BSL-2 for the study and believes it should be done at BSL2+. Bastian is not a microbiologist and the reviewer is not convinced he knows what BSL2+ is. He stated that this disease cannot be destroyed by normal decontamination methods. One committee member stated he went over SOP's with Bastian and developed a special one for this agent. He also noted it is destroyed with Clorox.
   Another committee member has concerns about the autoclave length. She also stated that decontamination of the cabinet needs to be done with a specific cleanser. She wants Bastian to submit an application for use of infectious agents (The IBC will send to him via email). Use of DNA is fine as proposed. The reviewer moved for approval at BSL-2+ and that the PI to submit an application for use of infectious agents. Approved unanimously after proper second.

4. **#0506042, Robert, Gary, "**[redacted]

   Garry stated that he will not have the whole virus here. He also stated that he could replicate it if he wanted to, but is not proposed. The virus will be obtained from USAMRIID and cloned there also. He will be using the virus to create high levels of antigens for development use in the field. A committee member asked where will the liters 10 be developed (Gary replied that it will be done in Maryland). The reviewer believes BSL-2 is most appropriate. Also, the reviewer noted that this protocol is a model of the type of applications PI's should be submitting to the IBC for review.

   Another committee member asked whether there is a final check to determine the agent was contagious. Garry replied yes they do. Garry steps out of room. The protocol was unanimously approved upon a duly made motion and proper second. Garry returned to room following the vote.

5. **#0506043, Leung, Wai-Choi, "Nan spheres as Carriers for Molecules and Vectors"**

   Listed reviewer stated did not receive the protocol prior to meeting. Dr. Clements presents the protocol. Dr. Clements stated that this substantially the same as the Brody and Morris protocols approved at the June meeting. The protocol was unanimously approved upon a duly made motion and proper second.

6. . **#0506044, Ramamoorthy, Ramesh, "Virulence determinants of Borrelia burgdorferi"**

   The reviewer would like to know what BMPA-D genes are. Reviewer moved

approval at BSL-3 pending clarification of what BMPA-D is and assuming the gene is not toxic. The protocol was unanimously approved upon a duly made motion and proper second.

7. **#0506046, Charles, Miller, "1) Evaluating drug toxicity in humanized yeast. 2) Pheonotype of p23 null mice.**

   The reviewer stated these are really two studies described in one protocol. The first experiment will be cloning different protein expressions. The reviewer stated there is an insufficient description of vectors. Another member stated that this portion of the protocol seemed to be exempt. The reviewer stated the second experiment (study of phenotype of mice) needed to contain more information about how the study is being conducted (i.e. vivo or in vitro?)

8. **#0506047, Hill, Steven, (No title provided)**

   This protocol was sent in response to IACUC inquiry and was deferred from the May meeting. The reviewer recommended for approval at BSL-2. The Committee approved unanimously upon proper motion and second.

9. **#0506048, Marx, Preston, "Immune Response to VSH/HIV/SIV Hybrids in Macaques"**
   #050649 – HIV Vaccine Design and Development Teams, and
   #050650 – Antibody-effector function protection against HIV-1

   One member thought the PI provided the absolute minimum information requested in the IBC application. Another member requested a detailed description of de-containment and disposal practices in lab for all proposals.

   The reviewer for #050650 stated that the protocol does not answer any of the questions he wanted answered. He has questions regarding de-containment and what specific training will be provided. The reviewer stated the committee needs to have SOPs and training materials with protocol in order to demonstrate a through review had been conducted. The committee decided that none of Dr. Marx's protocols were sufficiently explained. The committee requested clarification on responses to questions 9, 10 and 11. The committee asked for explanations of containment procedures PPE, and BSL levels on all three proposals. (Deferred unanimously).

10. **#0506051, Kuroda, Marcelo, "Cloning and expression of immune response genes"**

    The reviewer stated a detailed description of what genes will be expressed and what needed to be included in the protocol. The reviewer was clear on what will be done. Details also were requested on which cell lines will be used and details on de-containment procedures.

Another reviewer thinks Kuroda is a looking for blanket approval of his labs. He also believe this is exempt from a DNA standpoint (but probably needs infectious agent approval). The committee unanimously determined the protocol to be exempt upon a duly made motion and proper second.

11. **#0506053, Philipp, Mario, "Infectivity-associated Genes of Borrelia Burgdorferi"**

    The reviewer questioned the safety precautions of tick usage. The PI did not adequately describe which genes he is cloning or what genes he is knocking out. A motion was made to defer pending receipt of more information. The committee needs to know what the PI is purifying with the PQE. The reviewer will email his questions to Dr. Clements. The protocol was unanimously deferred pending answers to the committee's concerns.

12. **#0507054 Nickerson, Cheryl, "VEX-capture: A new technique that allows in-vivo excision, cloning, and broad-host range transfer of large bacterial genomic DNA segments**

    The reviewer requested for clarification on which of the biosafety levels will be used in the experiment. Nickerson stepped out of the room. One member stated he had a major problem as a scientist with moving large chunks of genes from one organism to another without knowing the consequences. In spite of his scientific reservations he believes the protocol should be approved at BSL-2. The reviewer moved approval with BSL-2 safety precautions for all phases of the study. Approved unanimously upon proper motion and second. Nickerson is asked to return.

New Business

Annual Registration

The forty-three (43) names of persons who completed the registration were read into the record.

} what record?

Dr. Clements suggest that all chairs be asked for names of PI's who do work with DNA because we have no way of knowing the percentage of compliance.

Approvals

Dr. Clements stated that Tulane PI's are the only PI's that can receive approval from our IBC. The IBC has two protocols submitted by non-Tulane PI's. From now on, the Tulane collaborator will have to be listed as the PI for purposes of the IBC application.

Proposed IBC Policy for Hazardous Biological

Dr. Clements announced that an IBC policy regarding the review of the use of hazardous biological materials is being developed. He also stated that the IBC need to define what it wants to know from PI's. This will be discussed further at the next meeting. Dr. Clements will distribute the draft manual so committee members can begin thinking about it.
The meeting was adjourned at approximately 2:18 p.m.

Faithfully submitted,

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John Clements, Ph.D., Chair

Tulane University
Institutional Biosafety Committee

Meeting Minutes
August 15, 2005

A meeting of the Tulane University Institutional Biosafety Committee (IBC) was held on the date set forth above, in room 504 of the J. Bennett Johnston Health and Environmental Research Building.

The following members of the IBC were in attendance:

John D. Clements - IBC Chair Microbiology/Immunology
Judy Anderson - Community Representative
James Balsamo - Director, Environmental Health & Safety
James Blanchard - Tulane National Primate Research Center – Veterinary
Bruce Bunnell – Gene Therapy
Robert Garry – Microbiology/Immunology
Gary Hole – Medicine – Pulmonary Diseases
Debra Jackson – Manager, Environmental Health and Safety
Nazih Nakhoul – Medicine – Nephrology
Cheryl Nickerson – Microbiology/Immunology
Vicki Traina-Dorge – Tulane National Primate Research Center – Microbiology
Tom Voss – Microbiology/Immunology
Weiping Zou – Medicine-Hematology-Oncology
Angelique Dorsey (ex-officio) – University Research Compliance Officer
Judy Taplin – (ex-officio) Compliance Officer Administrative Assistant

The chair called the meeting to order at approximately 12:05 p.m.

I. Approval of Minutes from Previous Meeting

Dr. Clements requested that IBC members review the draft minutes from the July 18, 2005 meeting of the IBC and provide comments, if any. With no comments or changes received, the minutes were unanimously approved upon a duly made motion and proper second.

II. Old Business

Dr. Clements stated that there were eight (8) protocols received from the Primate Center that were submitted at the last meeting that needed clarification. Dr. Clements also stated that there was not enough information in those protocols to do a stand up

review. Dr. Clements stated that three (3) investigators did not resubmit forms, Preston Marx, Charles Miller and Ivona, Pandrea, therefore we cannot act on them.

III. Protocols Review

1. **#0506030 – Bunnell, Bruce, "Development of in utero gene therapy procedures"**

   Dr. Bunnell submitted a clarification of his protocol as requested by the IBC at the July meeting. Dr. Clements discussed how Dr. Bunnell has address the committee's concerns. Upon proper motion and second the committee unanimously approved the protocol.

2. **#0506035 – Lackner, Andrew, "SIV Pathogenesis Study: IACUC Protocols #3245"**

   This is a resubmission of a protocol that was deferred from the June meeting Pending submission on the appropriate form. Upon proper motion and second, The committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this Proposal is BSL-2+ or BSL-2N+.

3. **#0506036 – Lackner, Andrew, "TB Vaccine Study, IACUC Protocol #3337"**

   After considerable discussion, the committee requested clarification regarding the nature of the *M. tuberculosis* challenge strain and the fate of infected animals at the end of the study. Specifically, the committee requested information concerning any known antibiotic resistance markers on the challenge strain and what would become of animals that remained alive at the end of the study.

4. **#0506037 – Lackner, Andrew, "AIDS vaccine development: SHIV"**

   This is a resubmission of a protocol that was deferred from the June meeting pending submission of the appropriate form. Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this Proposal is BSL-2+ or BSL-2N+.

5. **#0506039 – Lackner, Andrew, "SIV Pathogenesis Study, IACUC Protocols #3245, 3283, 3405, 3396"**

   This is a resubmission of a protocol that was deferred from the June meeting

pending submission of the appropriate form. Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this Proposal is BSL-2+ or BSL-2N+.

6. **#0506040 – Apetrei, Cristian, " Pathogenesis of HIV-1 Group N in Rhesus Macaques"**

   The committee requires clarification regarding how plasma viral loads will be assessed. Specifically, if this is to be accomplished by PCR, do you have plans to clone and sequence the PCR products? If so, you will need to provide details of the cloning strategy and identify all hosts and vectors to be used. If you do not plan to assess viral load by PCR, please indicate how that will be accomplished.

7. **#0506041 – Apetrei, Cristian, "Pathogenesis of New SIVsm Lineages in Rhesus Macaques"**

   The committee requires clarification regarding how plasma viral loads will be assessed. Specifically, if this is to be accomplished by PCR, do you have plans to clone and sequence the PCR products? If so, you will need to provide details of the cloning strategy and identify all hosts and vectors to be used. If you do not plan to assess viral load by PCR, please indicate how that will be accomplished

8. **#0506045 – Sestak, Karol, "HIV and mucosal immune system: new vaccine strategies.**

   This is a resubmission of a protocol that was deferred from the June meeting pending submission of the appropriate form. Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this Proposal is BSL-2+ or BSL-2N+.

9. **#0506053 – Philipp, Mario, Infectivity-associated Genes of *Borrelia burgdorferi***

   This is a resubmission of a protocol that was deferred from the June meeting pending submission of the appropriate form. Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this proposal is BSL-2+.

10. #0507058 – Robert, Garry, "A human endogenous retrovirus related to MMTV"

There was general agreement that this protocol may, in fact, be Exempt under Section III.D.2.a of the Guidelines. Non-the-less, upon recommendation of the primary Reviewer and proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this proposal is BSL-2.

[redacted]#0507059 – Garry, Robert, [redacted]

Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this Proposal is BSL-2+.

12. #0507060 – Garry, Robert, "HIV-1 Tat modulation of HCV replication and pathogenesis"

Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIG Guidelines for Research Involving Recombinant DNA Molecules,* the appropriate bio-containment level for the research described in this Proposal is BSL-2+.

13. #0507061 – Kadowitz, Philip J., "Stem Cell Therapy for Pulmonary Hypertension"

After considerable discussion, the committee requested clarification regarding How laboratory spills will be decontaminated and how the Principal Investigator Will determine that the fraction of the Adeno-viral genome being utilized does not Lead to a productive infection. The IBC requires that those studies beconducted By the Principal Investigator at Tulane and that the determination not be based on Studies performed elsewhere.

14. #0507062 – Overby, Darryl R. – "Isolation and culture of Schlemm's canal endothelial cells from human corneoscleral rims"

This is an Applicatoin for Use of Human Tissues, Infectious Agents, Pathogens, or Toxins that does not involve use of rDNA. The PI proposes to use corneoscleral rims obtained following cornea transplant surgery to isolate Schlemm's canal endothelial cells. Upon proper motion and second, the committee unanimously approved the protocol and recommended BSL-2 containment and universal precautions.

15. #0507063 – Ling, Binhua, "GBV-C and SIV co-infection in rhesus macaques"

This is an Application for Use of Human Tissues, Infectious Agents, Pathogens, or Toxins that does not involve use of rDNA. The PI proposes to co-infect Rhesus macaques with two viruses, SIV and GBC-C, an RNA virus I the Flaviviridae family associated with hepatitis. Upon proper motion and second, the committee unanimously approved the protocol and determined that the research described in this proposal is BSL-2+ or BSL-2N+.

16. #0508064 – Delafontaine, Patrice, "IGF-1 and Atherosclerosis"

This is an Application for Use of Human Tissues, Infectious Agents, Pathogens, Or Toxins that does involve use of rDNA. The committee requested clarification Regarding any special precautions taken with respect to aerosols generated during Centrifugation and how the Principal Investigator will determine that the fraction Of the Adeno-viral genome being utilized does not lead to a productive infection. The IBC requires that those studies be conducted by the Principal Investigator at Tulane and that the determination not be based on studies performed elsewhere.

17. #0504016, Godbey, WT "Transfection via Food Bourne Vectors, Pilot Study"

This is a resubmission of an application that was returned to the Principal Investigator because the application lacked sufficient information to allow the Committee to make a determination. After considerable discussion, the Committee voted to return the application to the PI again and request additional clarification.

IV. New Business

Dr. Clements asked committee how to proceed when a person is conducting a study on both rDNA and Infectious or Toxic Agents. He stated that most institutions have one form and all information would be listed on that form. Dr. Clements would like to move to one form. We have two forms, one for rDNA and one for use of Human Tissues, Infectious Agents, Pathogens or Toxins. The committee decided that for now, if both infectious agents and rDNA are used, the rDNA form should be submitted until a single form is developed.

The meeting was adjourned at approximately 1:52 p.m.

Faithfully submitted,

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John Clements, Ph.D., Chair

Tulane University
Institutional Biosafety Committee

Meeting Minutes
December 19, 2005

A meeting of the Tulane University Institutional Biosafety Committee (IBC) was held on the date set forth above, in room 603 of the J. Bennett Johnston Health and Environmental Research Building.

The following members of the IBC were in attendance:

John D. Clements - IBC Chair Microbiology/Immunology
James Balsamo - Director, Environmental Health & Safety
Bruce Bunnell – Gene Therapy
Robert Garry – Microbiology/Immunology
Gary Hole – Medicine – Pulmonary Diseases
Vicki Traina-Dorge – Tulane National Primate Research Center – Microbiology
Tom Voss – Microbiology/Immunology
Weiping Zou – Medicine-Hematology-Oncology
Judy Taplin – (ex-officio) Compliance Officer Administrative Assistant

The chair called the meeting to order at approximately 12:05 p.m. Dr. Clements also thanked everyone for attending meeting during this difficult time.

I. Approval of Minutes from Previous Meeting

Dr. Clements requested that IBC members review the minutes from the August 16, 2005 meeting of the IBC and provide comments, if any. With no comments or changes received, the minutes were unanimously approved upon a duly made motion and proper second.

II. Old Business

Dr. Clements stated that he sent letters out from the August 15th meeting but most Investigators did not receive them before August 29th. No meeting has been held since then. Dr. Clements presented each committee member with an agenda which detailed the current status on new proposals to be reviewed; modified proposals; modifications requested with no response from PI; and approved protocols from the August 15th meeting.

Dr. Clements stated that if only one new protocol is received, there will not be a meeting. The protocol will be reviewed by email or held until the next scheduled meeting.

III. Protocols Review

1. **#0506048, Marx, Preston "Immune Responses to VSV/HIV/SIV Hybrids in macaques"**
   #0506049, Marx, Preston "HIV Vaccine Design and Development Teams"
   #0506050, Marx, Preston "Antibody effector function protection against HIV-1

   Dr. Clements stated that these proposals are the modifications the committee requested from the August 15th meeting. The reviewer stated that a letter was received from PI clarifying the questions raised at the last meeting. (See attached letter). Reviewer stated all questions were answered and the issues at hand were addressed. Reviewer requested that proposals #0506048, 0506049 and #0506050 be approved at BSL-2+. Upon proper motion and second the committee unanimously approved the protocol.

2. **#0506038, Bastian, Frank "Role of Spiroplasm in the pathogenesis of TSE"**

   The reviewer stated that this protocol is to evaluate tissue samples from animals and humans for the present of genetic material of Spiroplasm and Culturable Spiroplasm. Reviewer also stated information regarding safety glasses/goggles was not included in the proposal. Reviewer requested proposal be approved at BSL-2+ with a letter to PI requesting clarification on safety glasses/goggles. Upon proper motion and second the committee unanimously approved the protocol.

3. **#0507055, Rowan, Brian "Selenium regulation of estrogen receptor in breast cancer"**

   PI only submitted abstract from grant. Reviewer stated proposal does not have enough information to adequately review. Chairman will send letter to PI informing him that there is insufficient information to evaluate proposal and to please resubmit. All were in favor.

4. **#0508065, Levy, Laura "Recombinant feline leukemia viruses as tools to study pathogenesis"**

   Upon proper motion and second, the committee unanimously approved the protocol. In accordance with Section III-D of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, the appropriate bio-containment level for research described in this proposal is BSL-1 or BSL-1N.

5. **#0508066, Bunnell, Bruce "Development of stem cell-based therapeutics for Cystic Fibrosis"**

   The reviewer stated that the PI proposes to transfer the CFTR gene into human

mesenchymal stem cells using a human lentiviral vector system. The Reviewer explained that the vector system involves three plasmids, the HIV gag and pol genes, the CFTR gene, HIV LTR and packaging sequence and the VSV-G envelope glycoprotein. Upon proper motion and second the committee unanimously approved the protocol at BSL-2.

6. **#0508067, Pandrea, Ivona "Pathogenesis of SIVagm in African green Monkeys"**

The Reviewer stated this protocol is not rDNA procedure and PI should have filled out other form. PI check wrong box, "check box 4" instead of "box 6". He also stated SIVagm is an infectious virus with the potential to infect humans. Details were lacking regarding biosafety level. No evidence of aerosol transmission exists and all work is done in biosafety level 2+. Upon proper motion and second the committee unanimously approved the protocol at BSL-2+.

7. **#0511069, Clements, John "Cloning and expression of Y. pestis LcrV"**

Dr. Clements stated that the reviewer was in the building but not in the meeting today to present protocol. Dr. Clements asked that this protocol be deferred to the next meeting to give reviewer time to review and present at next meeting. All were in favor.

The secretary reminded everyone to email their biosketches to jtaplin@tulane.edu if they had not done so.

Dr. Clements suggested that Dr. Levy or Angelique Dorsey send welcome letters to the committee.

The meeting was adjourned at approximately 1:05 p.m.

Faithfully submitted,

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John Clements, Ph.D., Chair