THE UNIVERSITY OF TENNESSEE
Health Science Center

Institutional Biosafety Committee
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October 20, 2006

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

Dear Mr. Hammond:

This correspondence is in reply to your letter dated October 12, 2006. We apologize for any delay. Apparently your original letter was sent to an address for The University of Tennessee Health Science Center (UTHSC) Administration (8 South Dunlap St., Suite C109) that we no longer use and so I did not receive it. I am glad that you sent us a fax transmission.

Enclosed per your request, are copies of the UTHSC's Institutional Biosafety Committee's (IBC) monthly meeting minutes for the period April, 2003 through present. Prior to August, 2005, when I joined the IBC, the committee met as needed (typically three times a year) to consider registrations. Since I became Chair, the IBC has met monthly when there were registrations or other rDNA matters to be considered. Meetings were held on the following dates from January, 2003, to October 12, 2006, the latter being the date I received your request:

April 29, 2003	February 10, 2005	January 6, 2006	July 10, 2006
August 7, 2003	May 5, 2005	February 8, 2006	August 4, 2006
November 6, 2003	August 5, 2005	March 10, 2006	September 8, 2006
January 30, 2004	September 2, 2005	April 7, 2006	October 6, 2006
August 13, 2004	October 7, 2005	May 5, 2006	
October 1, 2004	December 2, 2005	June 2, 2006	

I have enclosed the minutes from all of these meetings except the most recent one held on October 6, 2006. These minutes are in preparation and will not be approved until the November, 2006 meeting. Pursuant to the NIH Guidelines, Section IV-B-2-a-(6) information identifying individuals who are conducting specific research studies has been deacted from the enclosed copies.

We trust that this information satisfies your request. If we can be of further assistance, please direct correspondence to: The University of Tennessee rDNA Institutional Biosafety Committee, 910 Madison Avenue, Suite 823, Memphis, TN 38163.

Sincerely,

Lorraine Albritton

Lorraine Albritton, Ph.D.
Chair, Institutional Biosafety Committee

LA/dj

Enclosures

cc: Kennard Brown
Leonard Johnson
Sandra Mays
Randall Nelson

Institutional Biosafety Committee Meeting
April 29, 2003

Present: Drs. Ryan, Bahouth, Brand, Khurana, Kriwacki, Taylor, Whitt, Hugh Teaford, Marion Johnson and Carol Baumgartner.

Absent: Drs. Fan, Lindquester and Deborah Smith.

Guest: Sobha Jaishankar

Dr. Ryan began the meeting with a short discussion of the meeting he attended in San Diego, hosted by the Federal/NIH. In order to meet the federal guidelines, the IBC meetings should be open and available to the public and should also consist of regular meetings.

Hugh Teaford noted that the certification of biosafety cabinets was not sent to the safety officer but should be.

#156 Dr. [redacted] Adenovius-mediated transfer of LPA receptor signaling.
Proposal approved at 3D level. The room numbers need to be in proposal and specs for usage on level 2 hoods.

#157 [redacted]: VSV as a vector for cytokine-assisted tularemia vaccines.
Committee moved that either a new or an addendum was needed before approval of proposal (1) Are select agents going to be used? (2) Resubmit BSL2 clarifying waste disposable. Committee placed on hold till next meeting.

Dr. [redacted] Mechanisms of CREB regulation by CD40 and BCR.
Committee approved 3E – BSL1

#159 [redacted]: Contribution of phospholipase D to angiotensin II- induced protein kinase B activation and vascular smooth muscle cell growth.
The committee wanted additional information on maintaining replication and more elaboration on vector. Will decide if BL2 3D or 3E by e-mail after addendum has been done.

#160 [redacted] Transfection of targeted acquorin in arterial smooth muscle.
Committee approved 3D BL2

#161 [redacted] Gene disruption in Candida albicans
Committee approved 3E BSL1.

#142 [redacted] Supplement to original protocol, Physiological functions of amyloid precursor protein.
Committee approval for 3D BSL2 contingent on addendum. The proposal needs to address health concerns on expression of amyloid precursor protein. He needs more elaboration on vector and also needs to put BSL2 in addendum. The committee would like to make sure he is up-to-date on protocols.

A brief business meeting followed review of the applications. Federal guidelines mandate open meetings, so the committee agreed to meet four times a year – target dates being February 1, May 1, August 1, November 1, at 4:00 pm which should allow researchers time to write grants and have committee review/approval before waiting until the meeting date or grant deadline. These meeting dates will be posted on an electronic calendar.

It was determined that submitting an electronic application would be helpful to committee members. [redacted], Committee Secretary, told members that option is available. Dr. [redacted] will draft a memo for Research Administration to send electronically to all faculty notifying them of the new meeting deadlines, and the process for submitting applications electronically. Dr. [redacted] could scan applications to [redacted] who could then send them out to all members, one month in advance, for a fast review. This would allow time for the researcher to answer any questions or concerns with the application before the full committee meeting time. A hard copy with Principal Investigator and Department Chairman's signature would need to be given to Research Administration. We could also put training procedures on the web. It was also agreed that Dr. [redacted] would have the authority to review applications before submission to committee members, and give approval for all BL1 level applications without committee review. Tentative approval was also given for conditions for expedited review – Dr [redacted] agreed to work on this.

Dr. [redacted] will be appointing a special ad hoc committee to the IBC to investigate applications using select agents. These applications will need select agent approval before their initiation. Dr. [redacted] indicated that he is working toward this goal, but there is much work to be done. It is possible that MTA's will require a special box, on the questionnaire, to indicate whether or not they involve "select agents".

UT needs to investigate and implement training for research on correct laboratory and waste disposal procedures. The committee recommended that inspection of biosafety hoods in labs on campus should be done periodically. Committee is hopeful that manuals can be found to help with this training. The CDC has slides on power point that could be made available on our website. Dr. [redacted] noted that he served on the IBC at St. Jude and it was necessary to take a website exam in order to serve on the committee.

It was noted there is a need for some changes in the committee makeup, including a new outside person with no connection to UT. Possible new members might be Dr. [redacted], or an attorney, if one could be found willing to serve.

The government is very interested in wanting to know if pathogens are on campus, and we can look forward to unexpected visits from examiners. Everyone agreed that this is a most important issue, and needs to be addressed.

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting
Molecular Sciences Building, Room 201A
August 7, 2003, 4:00 pm.
Minutes

Present: Drs. Pat Ryan, Seema Khurana, Richard Kriwacki, Bill Taylor, Michael Whitt, Sobha Jaishankar, and Ms. Caffie Underwood, Committee Secretary.

Absent: Drs. Suleiman Bahouth, David Brand, Bin Fan, Gary Lindquester and Mr. Hugh Teaford.

Guest: Ms. Janie Gardner, Compliance Officer for the Office of Human Subject Protections

At the regular meeting of the IBC committee, Dr. Ryan opened the meeting with a discussion of old business. An online application has not been completed but will be scheduled in the future. Software for training will be placed on the web.

Two personnel changes were announced. Dr. Sobha Jaishankar is replacing Dr. Deborah Smith on the committee and Ms. Caffie Underwood is replacing Ms. Marian Johnson who is retiring.

Action on Protocols:

#163 – [redacted] Adenylyl cyclase as a regulator of cardiac fibroblasts.
This protocol was approved at BL2 – 3D level.

#165 – [redacted] Lentiviral-mediated gene delivery to the RPE.
This protocol was approved at BL2 – 3D level.

#166 – [redacted] Role of TauT in cisplatin-induced nephrotoxicity.
This protocol will be held for further revisions. The applicant needs to describe the vector and the construction of transgenic mice in more detail. Dr. [redacted] will poll the committee by e-mail for approval after all revisions have been met.

The meeting adjourned at 4:30 pm.

Respectfully submitted,

[redacted]
Clerk

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting
Molecular Sciences Building, Room 201A
November 6, 2003 4:00 pm.
Minutes

Present: Drs. Pat Ryan, Seema Khurana, Richard Kriwacki, Bill Taylor, David Brand, Suleiman Bahouth and Gary Lindquester.

Absent: Drs. Zheng Fan, Sobha Jaishanka and Michael Whitt.

The minutes from the last meeting were approved without correction.

There is now an on-line application. It cannot be submitted on-line, but can be printed out and submitted. There will have to be a separate form for select agents, which is being designed by Dr. [redacted] for the committees review. It will contain pertinent questions dealing with select agents.

The committee still has one more outside member to select.

Action on Protocols:

#157: [redacted] VSV as a vector for cytokine assisted tularemia vaccines.
This protocol is being resubmitted from April. Full approval at BL2–3D is contingent on the assurance that he will check for replication competence on each prepared lysate.

#167: [redacted] Genetic Analysis of Francisella Outer Membrane Proteins.
This protocol is on hold pending revisions, approval from the ad hoc committee on select agents, and approval from HHS.

#168: [redacted] Physical and functional coupling of beta 2 adrenergic receptor and CFTR #2.
This protocol has full approval at BL2-3D with clarifications about the type of flow hood and disposal of solid waste products.

#169: [redacted] Induction of immunological paralysis of CpG DNA.
This protocol has full approval at BL2-3E level.

The meeting adjourned at 4:30pm.

Respectfully submitted,

[redacted]
Clerk

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting
Molecular Sciences Building, Room 201A
January 30, 2004 2:00pm
Minutes

Present: Drs. Pat Ryan, Richard Kriwacki, Bill Taylor, David Brand, Suleiman Bahouth and Gary Lindquester, Sobha Jaishankar.

Absent: Drs. Zheng Fan, Seema Khurana and Michael Whitt.

The minutes from the last meeting were approved without correction.

Action on Protocols:

#64 [redacted] **Viral proteins for gene delivery to specific malignancies:**
This is a revised protocol. She is being asked to write a new protocol for review. She will be given a list of requirements and after writing the new protocol and meeting the requirements the protocol will be approved.

#171 [redacted] **Role of MLFIIP in cancer and normal development:**
Deemed exempt by the Chair's initial review.

#172 [redacted] **The influence of bicarbonate on Gap junction communication:**
Deemed exempt by the Chair's initial review.

The meeting adjourned at 2:45pm

Respectfully submitted,

[redacted]
Clerk

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting
Molecular Sciences Building, Room 201A
August 13, 2004, 4:00 pm
Minutes

Present:	Pat Ryan, Ph.D., Chair	Suleiman W. Bahouth, Ph.D.
	David Brand, Ph.D.	Richard W. Kriwacki, Ph.D.
	Gary J. Lindquester, Ph.D.	William L. Taylor, Ph.D.
	Zheng Fan, Ph.D.	Michael A. Whitt, Ph.D.
	Kathy Germain, M.S.	Sobha Jaishankar, Ph.D.
Administrative:	Melanie Saucier, Janie Vanprooijen	

Absent: Seema Khurana, Ph.D.

Dr. Ryan and the committee approved minutes of the last meeting for May.

[redacted] has requested a list of personnel who has access to the BSL3 Lab.

There was a personnel change for administrative duties for the rDNA Committee. [redacted] is now the acting Administrative Assistant.

Action on Protocols:

#177 – [redacted]: NFATs and Vascular Injury 2. PLA_2 and Vascular Wall Remodeling 3. Eicosanoids and Angiogenesis

This protocol was approved at BL2 – IIID level.

#178 – [redacted] Hormonal Regulation of Fatty Acid Oxidation

The IBC is specifically requesting more detailed information on the proposed safety handling of materials (item #5), i.e., what else is planned beyond treating dishes with chlorox?

The IBC expressed its concern that your application has suggested BL-1 containment. The work must be performed at BL-2. The IBC also urges you to submit any other protocols dealing with adenovirus vectors.

This protocol approval is contingent needing more information.

#179 – [redacted]: A Phase II Double-Blind, Randomized, Placebo-Controlled Study to Assess the Safety and Efficacy of AMG0002 to Improve Perfusion in Critical Leg Ischemia (AG-CL1-0202)

This protocol was approved at BL1 – IIIC level

#180 – [redacted] Reactive Nitrogen Species and Accelerated Atheroschlerosis in Type I Diabetes

This protocol was approved at BL2 – IIID level

#181 – [redacted]: Identification and Characterization of Virulence Genes in Francisella LVS

The IBC is specifically requesting the following:

1. What is the basis for classification of LVS as a BL-2 level organism? Should this classification be reconsidered due to the introduction of antibiotic resistance?

2. List specific vectors to be used and applicable references.

3. Limit and specify the exact antibiotics to be used in the protocol.

4. In general, provide more detailed information on the safety precautions to be used while propagating and handling LVS.

5. Provide examples of "phenotypes of interest," i.e., what criteria will be used to identify genes for reintroduction into LVS, or will all clones be re-introduced? In this discussion, provide a general rationale and goal of the project.

#182 – [redacted]: Transposon Mutagenesis of Vibrio Cholerae

The IBC is specifically requesting the following:

1. List specific vectors to be used and applicable references.

2. Limit and specify the exact antibiotics to be used in the protocol.

3. Cite a reference, if possible, for the assumption that mariner-family transposons will not likely propagate in bacteria.

4. Describe more precisely the mutant phenotypes you will choose for additional studies such as reintroduction into *V. cholerae*. In this discussion, provide a general rationale and goal of the project.

#183 – [redacted]: Identification and Characterization of Vibrio Cholerae

The IBC is specifically requesting the following:

1. List specific vectors to be used and applicable references.

2. Limit and specify the exact antibiotics to be used in the protocol.

3. You note that enterotoxin-encoding genes will not be expressed. However, describe more precisely the genes you will choose for additional studies such as reintroduction into *V. cholerae*. In this discussion, provide a general rationale and goal of the project.

#184 – [redacted]: Bioavailability and Biodistribution Studies of Antisense Oligonucleotide Dosage Forms in Dogs

This protocol is exempt. Approved at IIIF level.

New business: Dr. Pat Ryan has announced to the Committee that he will step down from rDNA chair when his replacement is appointed.

[redacted] voiced that she has access to a variety of protocol Approval Request Forms she will submit to the Committee.

The rDNA Committee agreed to close this meeting at 5:30 pm and will reconvene in early November 2004.

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting
Molecular Sciences Building, Room 201A
October 1, 2004, 3:30 pm
Minutes

Present: Pat Ryan, Ph.D., Chair; David Brand, Ph.D.; Gary J. Lindquester, Ph.D.; Seema Khurana, Ph.D.; Suleiman W. Bahouth, Ph.D.; Richard W. Kriwacki, Ph.D.; John Bossier, Safety Advisor; Michael A. Whitt, Ph.D.

Administrative: Melanie Saucier

Absent: Zheng Fan, Ph.D.; Kathy Germain, M.S.; Sobha Jaishankar, Ph.D.

Dr. Ryan and the committee approved minutes of the last meeting for August.

Action on Protocols:

#181 – [redacted] (Revised): Recombinant expression of Francisella tularensis genes in E. coli

Revision was accepted and protocol was approved at BL2 – IIIE level.

#185 – [redacted] The role of nitric oxide in vascular injury-induced neointima formation

Approved IIID BL2

#186 – [redacted] Interferon-beta gene therapy for pediatric glioma

Approved IIID BL2

#187 – [redacted] Cooperative regulation of MRP2 and CFTR in lung epithelial cells

Exempt

#188 – [redacted] TBP-independent activation of IFN-stimulated genes in VSV infections

Approved IIID BL2

#189– [redacted] Knockdown of neuronal nicotinic acetylcholine receptor (nAChR) subunit gene expression using siRNA expressed by lentiviral vector injected into rat brain

Approved IIID BL2

#190 – [redacted]: Growth factor and antiapoptotic gene delivery to human islets (1)

Approved at IIID BL1

#191 – [redacted]: Growth factor and antiapoptotic gene delivery to human islets (2)

Approved at IIID BL2

The committee noted that bleach should be used instead of ethanol to inactivate virus on surfaces.

#192 – [redacted]: Inhibition of hypersensitivity pneumonitis via inhibition of collagen production

Exempt

New business: Dr. Pat Ryan repeated his announcement to the Committee that he will step down from rDNA chair.

The rDNA Committee agreed to close this meeting at 5:30 pm and will reconvene in early December 2004.

University of Tennessee Health Science Center Institutional Biosafety Committee Meeting
Molecular Sciences Building, Room 201A, February 10, 2005 4:00pm
Minutes

Present: Drs. Pat Ryan, Bill Taylor, David Brant, Suleiman Bahouth, Gary Lindquester, Sobha Jaishankar, and Kathy Germain.

Absent: Drs. Zheng Fan, Seema Khurana, Michael Whitt and Richard Kriwacki.

The minutes from the last meeting were approved without correction.

Action on Protocols:

#178: [redacted]: Hormonal regulation of fatty acid oxidation. Dr [redacted] provided additional information on monitoring for replication competent adenoviruses which had been requested at the October meeting. Approved BL2, IIID.

#193: [redacted]. Porcine reproductive and respiratory syndrome (PRRS). Approved BL1, IIIF (deemed exempt by Pat Ryan prior to meeting).

#194: [redacted] Wnenv. Approved [redacted]

#195: [redacted]. Phase I study of recombinant oral BAH-2 Cholera vaccines in healthy adults. The committee wanted [redacted] to look at this one before full approval at BL2 IIIE. NOTE: approval given.

#196: [redacted] The role of PLA2 and serine 228, 505,515,727 mutants in vascular injury-induced neointima formation. The committee wanted this protocol switched to [redacted] and will request more explanation of how monitoring for replication competent adenoviruses will be performed. Approval at BL2 IIID contingent upon revisions.

#115 and 122: [redacted] Amendments to these protocols included the use of adenovirus vectors. The committee requested that new protocols be submitted rather than be included as amendments.

Old/New Business:

It was noted that renewal letters had been sent to investigators with an incorrect renewal date and that new letters would be sent.

Dr. Ryan announced his resignation as Chair effective February 28, 2005.

Dr. [redacted] announced that she is leaving the IBC and the University for a position at the University of [redacted].

Dr. [redacted] requested that the UT IBC serve as IBC for [redacted] protocols. The request was approved by the committee and had received previous approval by Associate Dean of Research [redacted]. Dr. [redacted] will serve as Chair of the [redacted] IBC.

The meeting adjourned at 4:45pm

Respectfully submitted,

[redacted]
Clerk

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting
Molecular Sciences Building, Room 201A, May 5, 2005, 4:00 pm
Minutes

Present: Drs. Pat Ryan, Bill Taylor, David Brand, Michael Whitt, Kathy Germain, Richard Kriwacki, and Zheng Fan

Absent: Drs. Suleiman Bahouth, Seema Khurana and Gary Lindquester

The minutes from the February 10, 2005 meeting were approved without correction.

Action on Protocols:

#197: [redacted] – Transfection of green fluorescent protein in arterial smooth muscle
Previously approved: project class level IIID BL2

#198: [redacted] – Role of CD9 in modulation of B cell phenotypes
IIID – BL2 – Full approval of the committee

#199: [redacted] – Role of CD9 in modulation of cell phenotypes
IIID – BL2 – Full approval of the committee

#200: [redacted] – VSV as a vector for cytokine-assisted tularemia vaccines (virulent strain)
IIID – BL2/3 – Full approval of the committee

#201: [redacted] – Infection of cameleons in arterial smooth musle
IIID – BL2 – Approval contingent upon revisions:

1. Should list Dr. Hassid as co-investigator
2. Provision for mask and eye protectors when working outside of the biosafety hood
3. Provision for packaging of virus in containers when moving from lab to lab
4. Provision for designating a room as operating at BL2 level

The meeting adjourned at 4:45pm

Respectfully submitted,

[redacted]
Clerk

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting Minutes
August 5, 2005

I. Call to Order

Lorraine Albritton, Ph.D. called to order the regular meeting of the Institutional Biosafety Committee Meeting at 4:00 p.m. on August 5, 2005 in Conference Room 201 of the Molecular Science Building.

II. List of Attendees

The following persons were present: Pat Ryan, Ph.D., Bill Taylor, Ph.D., David Brand, Ph.D., Michael Whitt, Ph.D., Suleiman W. Bahouth, Ph.D., and Zheng Fan, Ph.D.

III. List of Those Absent

The following persons were not in attendance: Kathy Germain, M.S., Seema Khurana, Ph.D., Richard W. Kriwacki, Ph.D., Gary Lindquester, Ph.D.

IV. Approval of Minutes from Last Meeting

The minutes dated 5/6/2005 were presented and approved without correction. Dr. [redacted] motioned to approve. Dr. [redacted] seconded the Motion. All committee members favored the approval of the minutes as presented.

V. Open Issues/New Business

a) Dr. Albritton was recognized as new chair person replacing Dr. Pat Ryan.
b) [redacted] was introduced as new committee administrative support staff replacing [redacted]
c) Handouts were distributed; obtained from the website of the NIH Office of Biotechnology Activities as follows:

- Dated 12/6/2004, Re: IBC Compliance with the NIH Guidelines ensuring that IBCs are properly constituted and functioning in full compliance with the NIH Guidelines
- Dated 5/14/2004, Re: Minutes of IBC Meetings
- Dated 2/01/02, Re: FAQS on registering new IBCs with OBA and Annual Reporting.
- Dated 4/24/2002, Re: FAQS on IBC Committee Membership

d) There was discussion of development of the IBC website. Committee members discussed addition of more extensive guidelines for rDNA applications and posting of recommended SOP and Accidental Spill Procedures.
e) Dr. [redacted] former IBC Chair, stated that IBC member's bios were updated in May, 2005 for the IBC annual report to NIH OBA.

VI. Action on Protocols

a) **Protocol #202** - Upon discussion of the classification and biosafety level the Committee voted unanimously for **Full Approval as Class III-E and BL-1.**

b) **Protocol #203** – Upon discussion of the classification and biosafety level the Committee voted unanimously for **Full Approval as Class III-D, BL-1** which is specified for all injection of naked DNA into rodents. The committee agreed to remind Dr. [redacted] that double gloves must be worn by personnel while performing injections of naked DNA into animals.

c) **Protocol #204** – Upon discussion of the classification and biosafety level the Committee voted unanimously for **Full Approval as Class III-D, BL-1** which is specified of naked DNA into non-human vertebrates, including vertebrate eggs. The committee agreed to remind Dr. [redacted] to ensure a mandatory requirement of the use of double gloves while performing injections of naked DNA.

d) **Protocol #205** – Upon discussion of the classification and biosafety level the Committee voted unanimously for **Approval as Class III-D under Bl-1** for working involving plasmid DNAs **and BL-2** for working involving adenoviral vectors, introduction of DNAs into cultured mammalian cells and adenoviral vector infected cells pending revisions to the protocol specifying:

1) all work involving adenoviral vectors, introduction of DNAs into cultured mammalian cells and adenoviral vector infected cells will be carried out in vent-cap canted neck flasks with filter cap membrane that are screwed tight at all times in which the flask is outside of the Class II Biosafety cabinet.
2) Flasks containing adenoviral vector infected cells and cells exposed to adenoviral vector plasmid DNAs will be closed tightly and placed in a sealed container during transport between the Class II Biosafety cabinet in Room [redacted] Building and the culture incubator in Room [redacted] Building to provide adequate containment in the event of accidental spill during transport.

e) Protocol #119 – An amendment to protocol #119 was brought before the committee and discussed. The committee requested additional information be submitted before they could vote. Further, a committee member requested the complete application of protocol #119 since its inception be made available to all members for review. The chair then asked if provided the request is met for additional information and complete application, would the committee vote their response via e-mail. The committee agreed to this request

VII. Adjournment

Dr. Albritton adjourned the meeting at 5:15 p.m.

Minutes taken by: [redacted]
Minutes approved by: Lorraine Albritton, Ph.D.

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting Minutes
September 2, 2005

I. *Call to Order*

Lorraine Albritton, Ph.D. called to order the regular meeting of the Institutional Biosafety Committee Meeting at 4:00 p.m. on September2, 2005 in Conference Room 201 of the Molecular Science Building.

II. *List of Attendees*

The following persons were present: Lorraine Albritton, Ph.D., Pat Ryan, Ph.D., Bill Taylor, Ph.D., Michael Whitt, Ph.D., Zheng Fan, Ph.D., Kathy Germain, M.S., Seema Khurana, Ph.D., Richard W. Kriwacki, Ph.D., and Gary Lindquester, Ph.D.

III. *List of Those Absent*

The following persons were not in attendance: David Brand, Ph.D., and Suleiman W. Bahouth, Ph.D

IV. *Approval of Minutes from Last Meeting*

The minutes of 8/5/2005 were presented and approved without correction. All committee members favored the approval of the minutes as presented. The chair recommended to committee members that upon receipt of monthly minutes, that corrections be forwarded to [redacted] in preparation for the next scheduled meeting.

V. *Action on Protocols*

a) **Protocol #119** - Upon discussion of the classification and biosafety level the committee agreed to approval the amendment as Class IIIE – BL-1 after revisions are made (reference – memo sent to Dr. [redacted] dated 9/1/2005), and a copy of the original protocol and signed letter stating the revisions are produced by Dr. [redacted]

b) **Protocol #205** – Upon discussion and revisions that were satisfied the Committee voted unanimously for **Approval as Class III-D under Bl-1** for working involving plasmid DNAs **and BL-2** for working involving adenoviral vectors, introduction of DNAs into cultured mammalian cells and adenoviral vector infected cells.

c) **Protocol #206 & 207** – The Chair explained why the protocols were not approved. Upon discussion it was determined that approval is pending.

provision of name and source of human cell lines and indicating whether they have been screened for viral pathogens.

VI. Open Issues/New Business

It was discussed and determined that the committee would began holding Monthly IBC Meetings on the first Friday of each month, unless there are no protocols pending; at which time, a cancellation notice would be sent one week prior to the scheduled meeting.

Committee members discussed and determined that after reviewing protocols, if there are revisions, questions or answers that are required from the PI before approval, and if they are satisfied by the PI as submitted, that it would not be necessary to meet on that particular protocol and that the Chair can approve and send out notifications as appropriate.

The committee members agreed that applications for review should be received by noon, on Friday, seven days prior to the next scheduled meeting.

There were discussions on the development of Standard Operating Procedures that will be made available on website. The following handouts were distributed and considered inserts for website development.

1. Pages from "Biosafety in Microbiological and Biomedical Laboratories 4th edition (April 1999) published by the CDC and NIH" – more information can be found by accessing: http:..www.cde.gov/od/ohs/pdfiles/4th%20BMBL.pdf

2. Information on Spill Response, Spill Clean-up BSL 1-2, and Biological Spill Clean-up Kit (Basic)

3. Website information on lentiviral vector safety and the risk from accidental exposure.

4. BSL2+ Biohazard Precautions.

5. A copy of Review/Approval Request Form with Experimental Procedure attachments.

The following modifications were recommended for the Review Approval Form:

1. An e-mail address for PIs will be added.

2. Page numbers will be added to assure that all are information is received and inclusive of signature lines.

3. Recommend an abstract be included

4. Name and location of "where to submit form" will be updated

5. Recommend that the form be user-friendly and formatted so that the PI can type in place of handwritten.

6. There was a recommendation to include (√) check- off points or, include a written statement that read s "I have read the BMBL appropriate sections and executed the appropriate procedures".

Comments and Recommendations for the SOP and Website Development:

The Chair stated that the IBC is responsible for the posting of the SOP Guidelines and that they should be made available for PIs to download. The Chair also stated that the IBC is responsible for the Institutions violations. The Chair then suggested that over the next year the committee spend 15 to 20 minutes during the meetings to recommend and began putting in place what material would be made available on the website. There was recommendation on what format would be used for directing PIs to procedure guidelines *(i.e., links, search, "for this, go here" etc.)*

In addition, there was recommendation for a request for inventory from PIs.

Most importantly, it was determined and strongly recommended by the committee members that a certified Bio Safety Officer is brought on board for the IBC. The Chair stated that a letter stressing the committees' strong recommendation and need for a certified BSO, along with supporting documentation as required by the NIH Guidelines be sent to the Chancellor. The letter will be forwarded to committee members prior to mailing out.

VII. Miscellaneous

The Chair presented a request from [redacted], Ph.D., [redacted], presently a member of UT IBC. Specifically, could the IBC here be formed into an IBC for [redacted] explained that two members from [redacted] would be in attendance (no voting privileges ?) and that the committee would probably address their issues no more than several times a year.

The committee members that were present agreed that they would support the request and would submit in writing to [redacted] their decision via e-mail. The Chair then stated that issues will be included on the IBC Agenda as needed.

VIII. Adjournment

Dr. Albritton adjourned the meeting at 5:15 p.m.

Minutes taken by: [redacted]
Minutes approved by: Lorraine Albritton, Ph.D.

University of Tennessee Health Science Center
Institutional Biosafety Committee Meeting Minutes
October 7, 2005

I. Call to Order

Acting Chair, Patrick Ryan, Ph.D. called to order the regular meeting of the Institutional Biosafety Committee Meeting. The meeting was called to order at 4:05 p.m. on October 7, 2005 in Conference Room 215 at the Student Alumni Center, 800 Madison Avenue.

II. List of Attendees

The following persons were present: Pat Ryan, Ph.D., Bill Taylor, Ph.D., Michael Whitt, Ph.D., Seema Khurana, Ph.D., Richard W. Kriwacki, Ph.D., Suleiman W. Bahouth, Ph.D., and David Brand, Ph.D.

III. List of Those Absent

The following persons were not in attendance: Lorraine Albritton, Ph.D. (Chair), Kathy Germain, MS, Zheng Fan, Ph.D., and Gary Lindquester, Ph.D.

IV. Approval of Minutes from Last Meeting

The minutes of September 2, 2005 were presented and unanimously approved by the committee members without correction.

V. Old Business

A draft copy of a letter to the Chancellor was presented. The letter expressed the committees' strong recommendation of the need for a certified BSO (Biosafety Officer) for the UTSHSC campus; and included supported documentation as required by NIH Guidelines. The committee agreed that the letter should be sent to the Chancellor after the following revisions were made; change the word "qualified" to "certified" and re-type the letter on updated (IBC) letterhead. [redacted] informed the committee that since the September 2, 2005 IBC Meeting, Chancellor [redacted] initiated a national search for a BSO. The matter of the appropriateness of the letter at this stage will be referred to Dr. [redacted]

VI. Action on Protocols

a) Protocol #206 - Upon discussion of the classification and biosafety level the committee agreed that protocol #206 be approved as exempt after revision that deletes Item 3 use of the vectors to transfect human cell lines.

b) **Protocol #207** – Upon discussion and review of revisions (addendum attached, identify cell lines) Committee voted unanimously for Approval as Class III-D BL-2.

c) **Protocol #208** – The Committee discussed several deficiencies provided by Dr. [redacted]

1. What is the name of the lentiviral vector in which the CFTR and mutant CFTR genes will be inserted? Please provide a genetic map of this vector or a list of the important features. Is it an HIV-based vector or other lentiviral vector?

2. At what location and by whom will the recombinant lentiviral vector particles be produced?

3. What system of production will be used? Specifically, how many other plasmids will be used to produce the lentiviral vectors and what viral genes are encoded on each of these other plasmids? If cells will be obtained through collaboration, MTA or purchase that already contain the viral genes for lentiviral vector production, then please supply similar information on the viral gene content of these cells.

4. Will each lentiviral vector production be tested for presence of Replication Competent Lentivirus (RCL)? If testing will be performed, please state who will perform the testing and describe the method of RCL testing. Indicate the source and nature of the controls to be used in the RCL assay and what you will do if the vectors test positive for RCL.

5. What will the Standard Operating Procedure be for maintaining biosafety during performance of cell culture experiments? Include protection equipment instructions, disposal and disinfection techniques, and storage and transport methods for lentiviral vectors, exposed cells and cell-derived samples.

In addition, committee also wants investigator to provide justification for use of lentivirus instead of a noninfectious vector.

As Dr. [redacted] would need to be excused from the meeting, (Protocols 209-211 submitted by [redacted] – up for review) the Chair asked committee members if

there were new items to add to the Agenda for the next scheduled meeting. No new items were noted, and Dr. [redacted] was excused.

VI. Action on Protocols cont.

d. **Protocol #209** – Upon discussion of classification and Biosafety level the committee unanimously approved Class IIID, BL-1, BL-2 as indicated from Investigator.

e. **Protocol #210** – Upon discussion of classification and Biosafety level the committee unanimously approved Class IIID, BL-1, BL-2 as indicated from Investigator.

f. **Protocol #211** – Upon discussion and review the committee recommended that they get the opinion of the BL3 Committee to determine containment level. Reference NIH Guidelines, Section III-D-3, attached)

VII. Adjournment

Dr. Ryan adjourned the meeting at 4:40 p.m.

Minutes taken by: [redacted]
Minutes approved by: Patrick Ryan

University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
December 2, 2005

I. Call to Order

Lorraine Albritton, Ph.D. and Chair called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:05 p.m. on December 2, 2006 in Conference Room 215 at the Student Alumni Center, 800 Madison Avenue.

II. List of Attendees

The following persons were present: Lorraine Albritton, Ph.D., Pat Ryan, Ph.D., Bill Taylor, Ph.D., Michael Whitt, Ph.D., Seema Khurana, Ph.D., Richard W. Kriwacki, Ph.D., Kathy Germain, M.S., and Zeng Fan, Ph.D.

III. List of Those Absent

The following persons were not in attendance: Suleiman Bahouth, David Brand, Ph.D. and Gary Lindquester, Ph.D.

IV. Approval of Minutes from Last Meeting

The minutes of October 7, 2005 were presented. A grammatical correction from "revision" to "revisions" was noted. Dr. [redacted] made a motion to approve. Dr. [redacted] second the motion, following a unanimous vote of approval of the minutes.

V. Old Business

Status of Protocol #211 – Principal investigator and IBC rDNA committee board member Dr. [redacted] informed the committee that he would like protocol #211 put on hold for further review of the IBC upon his response to the BL3 Committee's request for a risk assessment. The committee unanimously agreed to put this protocol on hold.

VI. New Business

Action on Protocols

a) Protocol #212 - Upon discussion of classification and biosafety level the committee unanimously approved of Class IIID, BL2 as indicated from Investigator.

b) Revised Protocol #00150 – Upon discussion and review of the committee, protocol 00150 is pending approval contingent on clarification from the investigator on application, specifically:
- How will you test for non-replication competent adenoviruses?
- How will RCA be monitored?
- How is RCA measured?
- What will be done if RCAs are detected?
- What was the rationale for using viral vectors versus transfection?
- Describe the practices at BSL-2 level

Due to the pending status, the investigator will be advised that all work performed in this study must cease and desist until additional information is provided and reviewed again by the Board.

In addition, the investigator will be informed that; for clarification purposes, when requesting revisions to an existing protocol, the committee recommends and requires that an investigator submit a cover letter specifying their revisions and detailing the changes.

c) Protocol #213 – Upon discussion and review protocol #213 is pending approval contingent on revisions and review of the following response from investigator, specifically:
- What cells will be used, E.coli and/or mammalian cells?
- List cells separately (item #3)
- Will viruses be used for cell infections?
- Why are viral infections listed in item #5?
- Will plasmids just be grown?
- Are plasmid vectors to be used in vitro transfection?
- There are no eukaryotic cells listed, but expressions described (explain)

VII. Miscellaneous

The Chair informed the committee of an NIH/OBA ruling that prohibits a vote of approval on application by way of e-mail. The ruling was based on the view that an e-mail vote could not appropriate the terms of defining "public access" to IBC meetings to include consensus.

The Chair informed the committee that though there could not be a vote by e-mail, that their comments and recommendations on protocols are still recommended via e-mail, as this would assist an investigator if additional information is required prior to the meeting.

There was a brief discussion on the search of a Biosafety Officer for UT IBC. The search is in progress and the position is expected to be filled in or about the month of July of 2006.

The Chair requested newly appointed Assistant Vice Chancellor for Research, [redacted] name be added to the IBC e-mail distribution list.

It was discussed, and unanimously agreed by committee members that any applications submitted with a BSL2+ would go before the BL3 committee for review and recommendation to the rDNA committee.

There was discussion on how to respond to a request from an investigator for the names of other investigators that are using the same vectors and how much information should be disclosed. It was recommended to a) send out an e-mail to all investigators asking if we have permission to give their name if there is an inquiry or; b) give a courtesy call to the investigator per request. At any rate, the committee unanimously agreed that unless authorized, no information should be released.

Several recommendations for modification of the Review/Approval form for the web site were as follows:

1. **Under Item #3** add "**Item #3a.** What vectors? **Item 3b.** What host?

2. **Under Item #4** (clarify the use on mammalian cells)

3. **Under Item #5** (insert)

   Note: If you have designated BL2 or higher you must know the appropriate procedures to follow while performing the studies under this protocol and sign one of the following statements:

   "I have read the appropriate sections of the BMBL Guidelines and agree to use the appropriate procedures from these guidelines when performing the studies by this protocol".

   _____ _____
   Principal Investigator **Date**

   "I have not read the appropriate sections of the BMBL Guidelines to use the appropriate procedures when performing the studies by this protocol".

   _____ _____
   Principal Investigator **Date**

4. **Under Item #9** - Include in your abstract, which should explain in layman terms, what you are going to do with the recombinant DNA. Give a brief narrative of the goals and experimental procedures so as to provide a basis for review. If you are going to use viral vectors, justify the use of an infectious agent over methods that do not involve infectious agents. Provide references and methods for your rationale.

Upon revisions of the review/approval form, the form will be distributed to committee members for approval before posting on the web.

Just before the close of the meeting, [redacted] asked permission to invite an assistant professor of natural sciences and director of Biotechnology Technician Programs from Southwest Tennessee Community College as an observer to the meeting. The Chair reaffirmed NIH regulations that opens an IBC meeting to the public, and welcomed the presence of Dr. [redacted]

Adjournment

Dr. Albritton adjourned the meeting at 5.10 p.m.

Minutes taken by: [redacted]
Minutes approved by: Lorraine Albritton, Ph.D., Chair, IBC

University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
January 6, 2006

I. Call to Order

Lorraine Albritton, Ph.D. and Chair called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:05 p.m. on January 6, 2006 in Conference Room 215 at the Student Alumni Center, 800 Madison Avenue.

II. List of Attendees

The following were present: Lorraine Albritton, Ph.D., Pat Ryan, Ph.D., Suleiman W. Bahouth, Ph.D., David Brand, Ph.D., Bill Taylor, Ph.D., Michael Whitt, Ph.D., Seema Khurana, Ph.D., Richard W. Kriwacki, Ph.D., Kathy Germain, M.S. and Gary Lindquester, Ph.D.

III. List of Those Absent

The following was not in attendance: Zheng Fan, Ph.D.

IV. Others Present

Randall Nelson, Ph.D., Assistant Vice Chancellor for Research, and Darlene Loprete, acting IBC chair, Rhodes College

V. Approval of Minutes from Last Meeting

The Minutes of December 2, 2005 were presented. A grammatical error of the word "Principle" was noted and corrected to read "Principal". The minutes were unanimously accepted by the committee.

The Chair introduced Dr. [redacted], Assistant Vice Chancellor for Research and informed the committee of his insightful position as it relates to the IBC.

VI. Old Business

Modifications of the Review/Approval form were presented. Recommendations were as follows:

Item #3 to include 3a. If one of the vectors is an infectious agent, list the factors which limit its infectivity. 3b. If viral vectors will be used, describe the method

by which vectors will be assayed for the presence of replication competent virus and state what will be done with vector productions that contain replication competent virus. 3c. If mammalian cells will be introduced into animals, an IRB approval or exemption letter must be obtained. In addition, vectors for Prokaryote and Euraryotic hosts will be listed separately.

Item #5 will include the Biosafety in Microbiological and Biomedical Laboratories (BMBL) web address. The statement "I have not read the appropriate sections of the bmbl guidelines to use the appropriate procedures when performing the studies by this protocol" and signature line will be omitted.

Item#9 will read: In the space below provide an abstract of the goals and objectives of the studies. Your abstract should explain in layman terms what you are going to do with the recombinant DNA. Give a brief narrative of the goals and experimental procedures so as to provide a basis for review. If you are going to use viral vectors, justify the use of an infectious agent over methods that do not involve infectious agents. Lines "Provide references and methods for your rational" and "Abstracts from grant applications can be used" will be omitted.

Public Notice of Meeting – The committee agreed that an announcement of the rDNA IBC meeting will be posted on the web to read: The Institutional Biosafety Committee (IBC) meets regularly on the first Friday of each month and is open to the public.

Protocol #00150R2 - Upon discussion of classification and biosafety level the committee unanimously approved Class IIID BL2 as indicated from investigator.

Protocol #213R2 – Upon discussion of classification and biosafety level the committee unanimously approved of Class IIIE BL2 in mammalian procedures, and Class IIIE BL1 for work in E.coli.

VII. New Business

Protocol #214 - Upon discussion of classification and biosafety level the committee voted approval contingent on revision to clarify the room number where experiment procedures for fly use will be performed, and revision of item 2 part d, to restrict use of new genes to those which are not oncogenes or toxins. Additional review and approval of the IBC is required for use of genes encoding oncogenes or toxins.

Protocol #215 – The committee agreed that the protocol would be held for review pending additional information. A letter with the committee's concerns will be sent to the principal investigator. Included in the letter would be the board

members recommendation that the investigator attend the next IBC meeting and give an overview of his research, and answer questions. The committee agreed that the attendance of the IACUC members would be significant in reviewing this protocol.

Protocol #216 – The committee agreed that the protocol would be held for review pending additional information. A letter with the committee's concerns will be sent to the principal investigator. Included in the letter would be the board members recommendation that the investigator attend the next IBC meeting and give an overview of his research, and answer questions. The committee agreed that the attendance of the IACUC members would be significant in reviewing this protocol.

VIII. Miscellaneous

The Chair informed the committee members of modifications to the annual review letters. Included will be attachments with statement and signature lines specifying pertinent changes including a "change in personnel form". Revised protocols will reflect the letter "R" and sequential numbers (ex. R1, R2) to show significant revisions in studies.

The committee agreed that an investigator submitting application for review involving work at BL1 or exempt can initiate his/her study before approval by the IBC. Work involving a BL2 or higher cannot be performed without IBC approval.

The committee agreed that if application is pending revisions for additional information and the investigator has completely satisfied the request of the committee, that the protocol will not have to be re-reviewed by the board, the Chair can make the final approval.

Adjournment

Dr. Albritton adjourned the meeting at 5.10 p.m.

Minutes taken by: [redacted]
Minutes approved by: Lorraine Albritton, Ph.D., Chair IBC

University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
February 8, 2006

I. Call to Order

Lorraine Albritton, Ph.D. and Chair called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:05 p.m. on February 8, 2006 in Conference Room 215 of the Student Alumni Center, 800 Madison Avenue.

II. List of Attendees

Lorraine Albritton, Ph.D., Pat Ryan, Ph.D., Suleiman W. Bahouth, Ph.D., David Brand, Ph.D., Bill Taylor, Ph.D., Michael Whitt, Ph.D., Richard W. Kriwacki, Ph.D., and Zheng Fan, Ph.D.

III. List of Those Absent

Gary Lindquester, Ph.D., Seema Khurana, Ph.D., and Kathy Germain, M.S.

IV. Others Present

Representatives of the IACUC included: Thaddius Nowak, Ph.D., Timothy Mandrell, D.V.M., Robert Parker, Ph.D., Patricia Farrar, D.V.M. Others present included: Randall Nelson, Ph.D., Assistant Vice Chancellor for Research, Mildred Randolph, D.V.M. PIs present: Aviv Hassid, Ph.D., and Yinzi Chang, Ph.D.

V. Approval of Minutes from Last Meeting

The minutes of January 6, 2006 were not presented but would be reviewed at the next IBC meeting.

VI. Old Business – Pending Protocols #215 & #216

The meeting began with a formal introduction of the members from the Institutional Animal Care and Use Committee, Institutional Biosafety Committee, and the presenters, Drs. [redacted] and [redacted]. Dr. [redacted] asked Drs. [redacted] and [redacted] to begin their presentation of Protocols #215 and #216.

The protocols were discussed extensively with Drs. [redacted] and [redacted] providing additional information in response to questions from IBC members and from

IACUC representatives. The committee decided that performance of the protocol in Dr. [redacted] wet lab space in the [redacted] Building posed too many biosafety issues. They recommended that a BL2 containment room be set up in the [redacted] facilities. Dr. [redacted] also felt this was the safest performance location. Dr. [redacted] stated that he anticipated this need and has located a room for the set up. The committee asked Drs. [redacted] and [redacted] to use this facility.

Dr. [redacted] and [redacted] expressed concern that it might be impossible to perform the surgical procedures prior to adenoviral vector injection. In response to their concerns, the committee asked that the PIs use the BL2 containment room in the [redacted] Building in a trial of the equipment in which the surgical procedure was performed followed by injection of mock virus. The committee will make a final determination on Protocols #215 and #216 after this trial.

Drs. [redacted] and [redacted] agreed to the proposed trial. Drs. [redacted] and [redacted] volunteered to assist them in arranging and performing the trial run.

Protocol #214 Upon discussion of classification and biosafety level the committee approved the protocol as Class IIID BL1, BL2 contingent on a letter of exemption from the IRB Committee.

VII. New Business

Protocol #217 Upon discussion of classification and biosafety level the committee unanimously approved of Class IIID BL1.

Protocol #218 Upon discussion of classification and biosafety level the committee is pending the protocol contingent on a request for additional information that will be forwarded to Dr. [redacted]

VIII. Adjournment

Dr. Albritton adjourned the meeting at 6:00 p.m.

Minutes taken by: [redacted]
Minutes approved by: Lorraine Albritton, Ph.D., Chair, IBC

University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
March 10, 2006

I. CALL TO ORDER

Lorraine Albritton, Ph.D. and Chair called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:15 p.m. on March 10, 2006 in Conference Room 215 of the Student Alumni Center, 800 Madison Avenue.

II. LIST OF ATTENDEES

Lorraine Albritton, Ph.D., Pat Ryan, Ph.D., Gary Lindquester, Ph.D., Seema Khurana, Ph.D., Bill Taylor, Ph.D., and Michael Whitt, Ph.D.

III. LIST OF THOSE ABSENT

Zheng Fan, Ph.D., Suleiman W. Bahouth, Ph.D., Richard W. Kriwacki, Ph.D., David Brand, Ph.D., and Kathy Germain, M.S.

IV. APPROVAL OF MINUTES

The minutes of January 6, 2006 and February 8, 2006 were presented. The minutes of January 6, 2006 and February 8, 2006 were unanimously approved without change.

V. OLD BUSINESS

Pending Protocols #215 & #216

The Chair informed the committee that the recommended trial run of a surgical procedures was performed using equipment in a BL2 containment room located in the Coleman Building. The Chair, and Drs. [redacted], (IACUC Chair) [redacted] (IACUC) and [redacted] (DVM) were present during the procedures. Dr. [redacted] informed the committee of the investigator's positive evaluation and comfort of the use of the equipment provided. Upon discussion, the board unanimously agreed that approval is pending the submission of a revised protocol and additional recommendations that will be forwarded to the investigator under separate cover.

Revised Protocol #169R1 Upon discussion of classification and biosafety level the committee agreed that the protocol is pending, contingent on recommended revisions sent to the investigator.

Revised Protocol #132R1 Upon discussion of classification and biosafety level the committee unanimously approved the protocol contingent on a detailed description of the assay to ensure no replication competent adenovirus is present. Upon satisfying the request, the Chair was instructed to make the ruling and decision on approval.

VI. NEW BUSINESS

Protocol #219 Upon discussion of classification and biosafety level the committee is pending the protocol contingent on a request for additional information that will be detailed and forwarded to the investigator.

Protocol #220 Upon discussion of classification and biosafety level the committee is pending the protocol contingent on a request for additional information that will be detailed and forwarded to theinvestigator

VII. ADJOURNMENT

Dr. Albritton adjourned the meeting at 5:15

Minutes Prepared by: [redacted]
Minutes Approved by: Lorraine Albritton, Ph.D., Chair, IBC

University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
April 7, 2006

I. CALL TO ORDER

Dr. Pat Ryan called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:15 p.m. on April 7, 2006, 910 Madison Avenue, Conference Room 801.

II. LIST OF ATTENDEES

Lorraine Albritton, Ph.D., Suleiman Bahouth, Ph.D., David Brand, Ph.D., Kathy Germain, MS, Richard Kriwacki, Ph.D., Pat Ryan, Ph.D., and William Taylor, Ph.D.,

III. LIST OF THOSE ABSENT

Zheng Fan, Ph.D., Gary Lindquester, Ph.D., Seema Khurana, Ph.D., and Michael Whitt, Ph.D.

IV. OTHERS PRESENT

Randall Nelson, Assistant Vice Chancellor Research, Dr. Amy Wadell, Southwest Community College

V. APPROVAL OF MINUTES

The minutes of March 10, 2006 were presented. Dr. [redacted]or made a motion to approve the minutes, Dr. [redacted] second the motion. A show of hands from board members unanimously approved the minutes without change.

VI. OLD BUSINESS

Revised Protocol #s 215 & 216

Approval is pending a written response from investigator to incorporate in the revised protocol the use of the latest standard operating procedures; that the lids on dirty cages will be replaced before removal from the biosafety cabinet and that the dead animals would be sealed inside a plastic bag before being placed in a red biohazard bag.

Upon receipt of clarification from the investigator, the committee voted that the the Chair would make the final ruling and a letter of approval will be sent. The committee would also need written clarification from the investigator as to whether protocol #216 is withdrawn.

At this time the meeting was turned over to Dr. [redacted] IBC Chair.

Revised Protocol #169R1 - Upon recommendation from the committee, new applications #224 & #225 were submitted. The committee agreed that Protocol 169R1 would revert back to the originally approved study under protocol #169 with only personnel changes.

Protocol #224 Upon review and discussion of protocol #224 the committee members request additional information. An itemized list of the specific pieces of information needed will be sent to the investigator under separate cover. Upon satisfactorily addressing each of these items, the revised application will be presented and reviewed at the next IBC meeting.

Protocol #225 Upon review and discussion of protocol #225 the committee members request additional information. An itemized list of the specific pieces of information needed will be sent to the investigator under separate cover. Upon satisfactorily addressing each of these items, the revised application will be presented and reviewed at the next IBC meeting

VI. NEW BUSINESS

Revised Protocol #223R Upon discussion of classification and biosafety level the committee is requesting the investigator to incorporate the updated version of the SOP, clarify testing for PTP13 activity, and describe how tissue would be handled post surgically. The protocol should include that work will be performed inside a Class II Biosafety Cabinet not just a "Culture Hood" since other types of culture hoods with less protection for users do exists. Upon satisfying the request the Chair would make the ruling.

Protocol #155R Upon discussion of classification and biosafety level the committee voted the protocol be held for revisions and response from the investigator on the following request: The investigator will incorporate and include in the revised protocol, the use of the newest version of the standard operating procedures, that the lids on dirty cages will be replaced before removal from the biosafety cabinet and that the dead animals would be sealed inside a plastic bag before being placed in a red biohazard bag.

The procedures for the handling of infected tissue after removal from study animal should also be stated in the protocol In addition, there should be clarification about whether only histological analysis will be performed.

Protocol #221R Upon discussion of classification and biosafety level the committee unanimously approved the protocol as Class IIIF BSLI (Exempt) as indicated by the investigator.

Protocol #222 Upon discussion and review of application the committee unanimously voted that the application is incomplete. The investigator will be informed that the application needs to be rewritten and the PI will be provided with resources to help carry out the committee's request. Upon receipt of completed application the protocol will be presented and reviewed at the next IBC meeting.

Protocol #218 –Upon discussion of classification and biosafety level the committee voted unanimously that the protocol be held until additional information is provided. An itemized list of concerns with recommendations will be sent to the investigator under separate cover. Upon satisfying the requests, application would be presented and reviewed at the next IBC meeting

VII. MISCELLANEOUS

The Chair informed the committee that we will begin sending out annual review letters on the anniversary of the IBC approval date which is the proper procedure and that included would be a portion where, if an investigator is using a class II safety hood we would request the investigator to send us a copy of the most recent certification for each of the biosafety hoods that they use. This would only be required for BL2 containment levels.

Dr. Albritton adjourned the meeting at 6:00 p.m.

VIII. NEXT MEETING

To be held on Friday, May 5, 2006, 4:00 p.m., 910 Madison Ave, Conference Room 801

Minutes Prepared by: [redacted]
Minutes Reviewed by: Lorraine Albritton, Ph.D., Chair, IBC

University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
Friday, May 5, 2006

I. CALL TO ORDER

Dr. Lorraine Albritton called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:10 p.m. on April 7, 2006, 910 Madison Avenue, Conference Room 801.

II. IBC MEMBERS IN ATTENDANCE

Lorraine Albritton, Ph.D., David Brand, Ph.D., Kathy Germain, MS, Michael Whitt, Ph.D., Pat Ryan, Ph.D., Zheng Fan, Ph.D., and William Taylor, Ph.D.

III. LIST OF THOSE ABSENT

Suleiman Bahouth, Ph.D., Richard Kriwacki, Ph.D., Gary Lindquester, Ph.D., and Seema Khurana, Ph.D.

IV. OTHERS PRESENT

Randall Nelson, Assistant Vice Chancellor for Research, Thad Nowak, Chair, IACUC, Amy Waddell, Southwest Tennessee Community College, and Ram Mahato, Ph.D.

V. APPROVAL OF MINUTES

The minutes of April 7, 2006 were presented. Several typographical errors were cited and noted. Dr. [redacted] made a motion to approve the minutes. [redacted] seconded the motion. There was one abstention, Dr. [redacted] who was absent from the meeting of April 7th. The remaining members where unanimous in approving the minutes as corrected.

VI. OLD BUSINESS

Status of Protocol #s 215R1, 155R1, and 223R1

At the March meeting the Chair was granted the final ruling by the IBC board members to approve each protocol upon review of revisions that would be incorporated and resubmitted in a revised protocol.

VI. NEW BUSINESS

The Chair informed the committee the recommendations had been incorporated in a revised protocol and therefore had been approved.

There was a brief discussion about modifications of the review/approval request form to assist an investigator in submitting revised protocols. After a short discussion, Dr. [redacted] suggested the committee look at a format that the IACUC used.

At approximately 4:30, Dr. [redacted] arrived to make a special presentation on protocol #191R4 entitled "Growth Factor and Antiapoptotic Gene Delivery to Human Islets".

The Chair gave a brief summary of the reason Dr. [redacted] the PI, and Dr. [redacted] Chair of IACUC were present, specifically a request from the IACUC for a review of Dr. [redacted] rDNA protocol. Dr. [redacted] brought the committee up to date with the issues of concerns to the IACUC. After Dr. [redacted] presentation there was a question and answer session with final recommendations for a revised protocol. Dr. [redacted] then left the meeting.

The IBC board members agreed that upon incorporating recommendations in a revised protocol, the Chair would make the final ruling for approval. A list of the recommendations will be sent to the investigator.

VI. NEW BUSINESS

Protocol #226 There were comments about why this protocol was being reviewed by the UTHSC rDNA Institutional Biosafety Committee as the study was being done at an off-campus site over which the university has no control and therefore could not enforce adherence to biosafety guidelines. Upon discussion, the IBC board members agreed that the matter should be referred to the Administration. Dr. [redacted] agreed to make the referral.

A motion was made that the IBC set a policy for handling off-campus applications; specifically, that the IBC Chair refer all applications for work at non-UT sites to the Assistant Vice Chancellor for Research, for an administrative decision without referral to full committee. The motion was seconded and passed by unanimous vote.

VII. ADJOURNMEMT

Dr. Albritton adjourned the meeting at 6:00 p.m.

VIII. NEXT MEETING

To be held on Friday, June 2, 2006, 4:00 p.m., 910 Madison Ave, Conference Room 801.

Minutes Prepared by: [redacted]
Minutes Reviewed by: Lorraine Albritton, Ph.D., Chair, IBC

The University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
Friday, June 2, 2006

I. CALL TO ORDER

Dr. Lorraine Albritton called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:05 p.m. on Friday, June 2, 2006, 910 Madison Avenue, Conference Room 801.

II. IBC MEMBERS IN ATTENDANCE

Lorraine Albritton, Ph.D., Kathy Germain, MS, Michael Whitt, Ph.D., Suleiman Bahouth, Ph.D., Richard Kriwacki, Ph.D., Seema Khurana, Ph.D., and William Taylor, Ph.D.

III. LIST OF THOSE ABSENT

Gary Lindquester, Ph.D., Zheng Fan, Ph.D., David Brand, Ph.D., and Pat Ryan, Ph.D.

IV. OTHERS PRESENT

Randall Nelson, Assistant Vice Chancellor for Research, and Amy Waddell, Southwest Tennessee Community College

The Chair opened the meeting by informing the members that they would review items that had not been reviewed in May's meeting, and that did not need a quorum vote since all the voting members had not yet arrived. The meeting began with the approval of the minutes.

V. APPROVAL OF MINUTES

The minutes of May 5, 2006 were presented. A typographical error was cited and noted. Dr. [redacted] made a motion to approve the minutes. Dr. [redacted] seconded the motion. The remaining members that were present were unanimous in approving the minutes as corrected.

The quorum was met and the Chair informed all of the reading and approval of the minutes and proceeded with the meeting; referencing "Web Page Development".

The Chair informed the members of progressive steps that have been taken in an effort to make the rDNA IBC web page available. Dr. [redacted] stated that drafts were made available and plans for distribution and review in May's meeting were delayed because the meeting had extended far beyond schedule.

The Chair then informed the board that in a discussion with Dr [redacted], Dr. [redacted] stated that there should not be any further delay for posting the information and that it could not wait for full committee review. Dr. [redacted] agreed that there was misinformation presently on the web, including old forms and then informed the committee that she updated and sent a draft formatted version to the appropriate IT personnel.

Dr. [redacted] asked that the committee members to review the drafts and come back to the next scheduled rDNA meeting with specific corrections or suggestions that would be helpful in the development of the web site. The discussion would be a priority and discussed at the next IBC meeting. In addition, Dr. [redacted] asked the board members for suggestions and recommendations for the development of SOPs and direct links for specific information i.e., the use of adenoviral, lentiviral, vectors etc.

The Chair informed the board that before the next meeting the administrative support person would send information on where to find the rDNA homepage.

VI. OLD BUSINESS

Protocol #219R2

The Chair informed the committee that the list of recommendations had been incorporated in a revised protocol. The committee agreed that an additional minor revision would need to be added into the protocol, specifically; how the virus would be contained and transported to the lab where work would be performed. The committee agreed that the Chair would make the final ruling once the request was satisfied. Dr. [redacted] made a motion that the Chair could approve the protocol. Dr. [redacted] seconded the motion. The remaining members were unanimous for the Chair to approve the protocol.

VII. NEW BUSINESS

Protocol #227

Dr. [redacted] informed the board that she had pre-viewed the protocol and sent a list of questions to the investigator who had responded. The list of the questions and responses were presented to the committee. The Chair then

asked if the board had any other concerns in addition to that which was presented. Dr. [redacted] made the motion for approval at IIID BSL2. Dr. [redacted] seconded the motion. The remaining members unanimously agreed for approval of protocol #227 as submitted.

Protocol #228

Upon review and discussion the committee agreed that there would be a need for revision; specifically 1. Title correction. 2. Under item 7 specify that the magnifying glass used during vector injections will be mounted stably to a platform that is a minimum of 3 inches up from the bottom of the front window of the class II biosafety hood. 3. Provide a statement that specifies that the procedures for the homogenization process will be performed in the class II biosafety hood. 4. Correct typographic errors that referenced BLS3 facilities (BL2 instead of BL3). 5. Limit proposed dates to a three-year period.. 6. Remove the procedure in which syringes and needles will be treated with 20% Clorox and replace with a procedure in which containment syringes and needles will be placed directly into a small biohazard sharps container within the class II biosafety hood. Dr [redacted] made a motion that the Chair would approve the protocol after the revisions. Dr. [redacted] seconded the motion. The remaining members unanimously voted the Chair to approve the protocol upon the investigator satisfying the recommended revisions.

Protocol 65R1

Upon review and discussion, the committee recommended the revisions be incorporated in the protocol, specifically; 1. Add to item 7 a statement that the investigator is either obtaining components of the pathogens from another investigator (give the name and institution) or a statement that all procedures with pathogens will be performed using BL2 precautions and procedures. 2. Change classification to IIIE with work performed at a BSL2 containment level. Upon satisfying the recommendations of the committee, the board unanimously agreed that the Chair would make the final ruling of approval.

Dr [redacted] and principal investigator of Protocol #229 was excused. Dr. [redacted] serving as interim Chair, presented a summary of protocol #229

Protocol #229

Upon review and discussion the committee unanimously approved protocol #229 at IIIE BL1 as submitted by investigator.

Protocol #230

Upon review and discussion the committee approved protocol #230 at IIID BL2 as submitted by investigator. Dr. [redacted] made a motion to approve. Dr. [redacted] seconded the motion. The remaining members voted unanimously for approval.

VIII. MISCELLANEOUS

Protocol #169

The Chair informed the committee that a follow up from an annual renewal request brought up concerns when an investigator indicated revisions other than personnel were needed but requested to revert back to the original protocol when told that a revised application would have to be submitted. After a brief discussion there was a motion to in-activate the file. This motion received a vote of two "for", and five "against". A second motion was made to give the investigator annual approval for the protocol #169 as written but excluding use of AAV and stating that if the investigator used any other viral vector in the future, a new protocol must be submitted before initiation of the work. This motion passed unanimously.

The annual approval letter approving the protocol until December 31, 2006 will include in the letter, the statements, "given that you expressed uncertainty in your e-mails to us as to what you might be doing in the future, the committee approved protocol #169 from January 1, 2006 to December 31, 2006, after which this protocol will be inactivated. To continue studies after December 31, 2006, a new protocol must be submitted before the experiments are initiated".

We advise that you submit any new protocol at least one month prior to the time you plan to initiate new studies. This will give time for the rDNA review.

Protocol #185

The protocol was brought in front of the board after a response to the annual renewal request letter. After a brief discussion the committee unanimously agreed that the protocol should be updated to incorporate the use of vectors that were approved in recently submitted studies. A letter will be sent to the investigator with the request to add an addendum that will incorporate the use of the vectors.

Protocol 233

The Chair informed the committee that this would be a new protocol due to a change in principal investigator. The Chair informed the committee that the initial protocol was inactivated due to the lack of response to the annual renewal

request for additional information. It was brought to the attention of the committee that the study was grant funded and it was recommended that the protocol be reactivated, however, the committee felt that there was insufficient information to make a ruling and there was a need for additional information. The committee unanimously agreed that a letter be sent to the investigator with the committees collective concerns.

Protocol 232

The Chair informed the committee that the protocol was not on the agenda and asked for volunteers for a pre-review. Drs. [redacted] and [redacted] along with Dr. [redacted] would pre-review and the request for additional information, if any, will be sent to the investigator and would pre-review the application along with Drs. [redacted] and [redacted]

X. OTHER POINTS OF DISCUSSION

Comments were made regarding the request for an MTA (Material Transfer Agreement) that is currently on the review/approval request form, and how relevant the attachment is when reviewing/approving protocols. After a brief discussion, the committee agreed that it was not a biosafety issue, but a legal issue of the Institution. The Chair made a recommendation that the notation: "If material was obtained under a Material Transfer Agreement (MTA), please attach a copy of the agreement" be removed from the form the next time the form is revised..

Dr. [redacted] made the motion for removal of the statement. Dr. [redacted] seconded the motion. The remaining members unanimously voted approval to remove the notation from the review/approval request form.

XI. ADJOURNMEMT

Dr. Albritton adjourned the meeting at 6:00 p.m.

XII. NEXT MEETING

To be held on Monday, July 10, 2006, 4:00 p.m., 910 Madison Ave, Conference Room 801.

Minutes Prepared by: [redacted]
Minutes Reviewed by: Lorraine Albritton, Ph.D., Chair, IBC

The University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
Monday, July 10, 2006

I. CALL TO ORDER

Dr. Lorraine Albritton called to order the regular meeting of the Institutional Biosafety rDNA Committee. The meeting was called to order at 4:10 p.m. on Monday, July 10, 2006, 910 Madison Avenue, Conference Room 801.

II. IBC MEMBERS IN ATTENDANCE

Lorraine Albritton, Ph.D., Michael Whitt, Ph.D., Suleiman Bahouth, Ph.D., Zheng Fan, Ph.D., David Brand, Ph.D., Pat Ryan, Ph.D., Gary Lindquester, Ph.D. Seema Khurana, Ph.D., and William Taylor, Ph.D.

III. LIST OF THOSE ABSENT

Kathy Germain, MS, and, Richard Kriwacki, Ph.D.

IV. APPROVAL OF MINUTES

The minutes of June 5, 2006 were presented. Dr. [redacted] made a motion to approve the minutes. Dr. [redacted] seconded the motion. The remaining members that were present were unanimous in approving the minutes as presented.

V. OLD BUSINESS

Protocol #224R1

After review and discussion, the committee recommended: 1) the classification be changed to IIID; 2) an example of the appropriate signage for biosafety level, and SOP for spills be forwarded to investigator that includes: investigator's contact information, with specific labeling that identifies the agent (s) that are being used, and the level of biosafety practices, i.e. BL2); 3) the investigator to specify in the protocol that cells would be homogenized under the class II biosafety cabinet; and; 4) the investigator to state in the protocol, that all work will be performed in the class II hood after transduction and until virus is inactivated (specify method of inactivation). Upon satisfying the recommended revisions, the committee unanimously agreed that the Chair could make the ruling to approve the protocol.

Protocol #225R1

After review and discussion, the committee recommended: 1) the classification be changed to IIID; 2) an example of the appropriate signage for biosafety level, and SOP for spills be forwarded to investigator that includes: investigator's contact information, with specific labeling that identifies the agent (s) that are being used, and the level of biosafety practices, i.e. BL2); 3) the investigator to specify in the protocol that cells would be homogenized under the class II biosafety cabinet; and; 4) the investigator to state in the protocol, that all work will be performed in the class II hood after transduction and until virus is inactivated (specify method of inactivation). Upon satisfying the recommended revisions, the committee unanimously agreed that the Chair could make the ruling to approve the protocol.

Web Development

Dr. [redacted] recommended we add/post the rDNA IBC meeting schedule to the web site. The Chair informed the committee that this was an NIH requirement and not only should the meeting schedule be posted, but the location as well. The committee agreed that the meeting schedule and location should be added to the web page.

There was discussion on adding links, with instructions, for the use of different agents. An option was to add a "forms" link with instructions for each agent., i.e. when using lentivirus, use this form; for retrovirus, use this form; if you are doing animal studies, use this form. There was a suggestion to add addendums to the review/approval request form, but that option was dismissed after the Chair brought to the committee's attention that addendums and attachments are often separated from the original signed protocol, and the separation of information would show an approval with what might appear an incomplete application.

Dr. [redacted] stated that identifying the IBC committee as the "rDNA" committee appears confusing to some and that the name "Institutional Biosafety Committee" should be more commonly used when identifying the board and its responsibilities.

Dr. [redacted] also recommended adding a notation to "class 4 agents", (under "Application for Review of Recombinant DNA IBC Check List") to read: "The University does not have facilities for use of Risk 4 agents.

There was a recommendation for a web designer to create the rDNA web site. Recommendations were made to look at other institution's web sites and protocol forms, and get approval from the institution to use their format. Dr. [redacted] commented that if we had permission to use other formats they could easily be downloaded and modified to fit the IBC's needs

Dr. [redacted] suggested that the committee hold off on updating the web page and protocol forms until the UT Biosafety Officer was brought on board in an effort to accommodate his/her input.

After much discussion, the Chair informed the committee that she would look at other institution's web pages and protocol applications, and select some that may prove promising for the IBC's use. She would review and forward to the administrator who would forward to board members for consideration and recommendations. The Chair asked the board to continue to work on the material that was presented and forward recommendations to the administrator within two weeks from the date of the meeting. The administrator would compile all information and prepare a draft for IT person.

Pre-review Protocol Assignments

After a brief discussion, it was determined that there would be a rotating list in which board members would review protocols. The administrator would send out protocols via e-mail to designated reviewers with a request that the reviewer respond with requests for additional information from the investigator within one week from the date of receipt of the protocol. The Chair and administrator will coordinate assignments.

VI. NEW BUSINESS

Protocol #231

Upon review and discussion, the committee recommended that the protocol is approved and an approval letter would be sent to the investigator that would include: 1) confirmation of project class of IIID; 2) a statement informing the investigator that when submitting protocols, if the only difference in the protocol is the nature of inserts and personnel involved, the investigator could use an amendment instead of submitting a new protocol. The committee agreed that the Chair could approve the protocol upon the investigator satisfying the revisions. Dr. [redacted] made a motion that the Chair approve the protocol with the statements addressed in the approval letter. Dr. [redacted] seconded the motion. The remaining members unanimously voted approval of the protocol upon the investigator satisfying the revisions.

Protocol #232

Upon review and discussion, the committee unanimously agreed that there was insufficient information to approve the protocol. A list of recommendations will

be forwarded to the investigator and upon a response from the investigator, the protocol would be brought back for full committee review. Dr. [redacted] made a motion for the protocol to remain in pending status until revisions were made. Dr. [redacted] seconded the motion. The remaining members agreed unanimously that the protocol would remain pending, contingent upon revisions and review.

Protocol #234

Upon review and discussion, the committee agreed that the investigator would need to provide additional information, specifically; 1) item #6, room numbers were inconsistent and will need to be clarified; 2) investigator needs to provide adequate signage (an example of proper signage will be forwarded); 3) the investigator would need to change item #8a. to yes, and complete item numbers 8b, and 8c; and, 4) the investigator would need to state in the protocol that the homogenization process will be performed under a class II biosafety hood.

Upon satisfying recommended revisions, the Chair would make the final approval. Dr. [redacted] made the motion for the Chair to make the final approval upon revisions. Dr. [redacted] seconded the motion. The remaining members voted unanimously to grant the Chair to approve the protocol upon revisions.

Protocol #235

Upon review and discussion, the committee voted full approval for the protocol as "exempt", with a classification of IIIF, as submitted by the investigator. By a show of hands the vote was unanimous.

VII. ADJOURNMENT

Dr. Albritton adjourned the meeting at 5:45 p.m.

VIII. NEXT MEETING

To be held on Friday, August 4, 2006, 4:00 p.m., 910 Madison Ave, Conference Room 801.

Minutes Prepared by: [redacted]
Minutes Reviewed by: Lorraine Albritton, Ph.D., Chair, IBC

The University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
Friday, August 4, 2006

I. CALL TO ORDER

Dr. Lorraine Albritton called to order the regular meeting of the Institutional Biosafety Committee. The meeting was called to order at 4:05 p.m. on Friday, August 4, 2006, 910 Madison Ave., Conference Room 801.

II. IBC MEMBERS IN ATTENDANCE

Drs. Lorraine Albritton, David Brand, Zheng Fan, Seema Khurana, Richard Kriwacki, Pat Ryan, William Taylor, and Michael Whitt

III. LIST OF THOSE ABSENT

Dr. Suleiman Bahouth, Kathy Germain, MS, and Dr. Gary Lindquester

IV. OTHERS PRESENT

Randall Nelson, Ph.D., Assistant Vice Chancellor for Research

V. APPROVAL OF THE MINUTES

The minutes of July 10, 2006 were presented. Dr. [redacted] made a motion to approve the minutes. Dr. [redacted] seconded the motion. The remaining members that were present unanimously approved the minutes as presented.

After the approval of the minutes, the Chair gave a brief summary of a pre-review format to be used in an effort to expedite the approval of protocols. The pre-review process would allow investigators to respond to recommendations from reviewers that satisfy specific requirements for completing applications. This would provide reviewers a better assessment for determining protocol approvals.

VI. OLD BUSINESS

Protocol #233R1

The reviewers informed the committee that there was no response to a request for additional information and that the protocol would need to be held for revisions and review. Dr. [redacted] recommended that in addition to the initial recommended request, the investigators should: 1) clarify what work will be done in BSL1, and what will be done in BSL2 containment; 2) item #7 - provide more information on retrovirus vector being used; 3) change the classification from class IIIA to class IIID. The committee agreed that

the Chair should send correspondence to the investigator requesting the additional information, and include in the correspondence, a statement expressing the importance of the requirements for approving protocols is based on the investigator addressing all the concerns and recommendations of the committee and incorporating them into a revised application. A motion was made by Dr. [redacted] to hold for revisions and review. Dr. [redacted] seconded the motion. The motion was approved unanimously.

Protocol #199R1
Upon review and discussion, the committee agreed and recommended the classification of BSL2. All that were present unanimously agreed upon approval.

Protocol #115R1
Upon review and discussion the committee voted full approval of Class IIIE BL2 as submitted by investigator. [redacted] made a motion for approval. Dr. [redacted] seconded the motion. The motion was unanimously approved.

Protocol #198R1
Upon review and discussion the committee agreed and recommended the classification be changed from class IIIE to class IIID. Upon the investigator satisfying the recommended request the committee agreed that the Chair would make the final rule of approval. Dr. [redacted] made the motion that the protocol be approved contingent upon the revision. Dr. [redacted] seconded the motion. The motion was unanimously approved.

Protocol #204R1
Upon review and discussion, the committee voted full approval of Class IIIF BSL1 as submitted by investigator. Dr. [redacted] made a motion to approve the protocol as is. Dr. [redacted] seconded the motion. All that were present unanimously approved the protocol as submitted by the investigator.

Protocol 185R1

Upon review and discussion, the committee voted full approval of Class IIID BL2 as submitted by investigator. Dr. [redacted] made a motion to approve the protocol as is. Dr. [redacted] seconded the motion. All that were present unanimously voted approval of the protocol as submitted by the investigator.

VII. NEW BUSINESS

Protocol #237

The reviewers informed the committee that there was no response to a request for additional information; therefore, the protocol would need to be held for revisions and review. Dr. [redacted] made a comment as to why the investigator did not include mammalian cells/eukaryotic under "key words" and recommended we add to the list of comments that were previously sent. Dr. [redacted] made a motion to hold the protocol for revisions and review. Dr. [redacted] seconded the motion. All that were present unanimously agreed that the protocol be held for revisions and review.

Protocol #236

Dr. [redacted] raised a question of why the investigator was using three different viruses and requested the investigator show justification. In addition, Dr. [redacted] wanted to know why the investigator did not submit separate protocols for each vector. The Chair informed the committee that while they agreed in the past that the investigators should use separate protocols for specific vectors, the format that this investigator used in this protocol, clearly identified each vector, the work that would be performed using each vector, and the biosafety procedures that would be used for each vector; therefore, this protocol should be considered using this format. Upon further review and discussion, the committee agreed that there was a need for additional information, specifically: Page 2 item 4a., No. 1, point 5 should be changed to read "use of a split three plasmid system....not split two; Page 3 item 2, point 5 should be changed to read "Use of a split five plasmid system "increases" the number, not "decreases" as written; Page 4, under PPE for Spill Procedures, and Spill Kit for Viral Vectors, specify that if using Clidox, it is made within two (2) weeks or omit and use fresh bleach; Page 5 under item 7, explain what types of analysis methods will be used on the tissues after infection? What precautions will be taken to prevent exposure to these infected tissues prior to inactivation of any residual virus?

Dr. [redacted] made a motion that the protocol be held for revisions and that the Chair would make the final rule of approval. Dr. [redacted] seconded the motion. The committee voted unanimously that the Chair could make the final rule of approval upon review of the recommended revisions.

VIII. **ADJOURNMENT**
Dr. [redacted] adjourned the meeting at 5:35 p.m.

IX. **NEXT MEETING**
To be held on Friday, September 8, 2006, 4:00 p.m., 910 Madison Ave., Conference Room 801.

Minutes Prepared by: [redacted]
Minutes Reviewed by: Lorraine Albritton, Ph.D., Chair, IBC

/dj

The University of Tennessee Health Science Center
Institutional Biosafety rDNA Committee Meeting Minutes
Friday, September 8, 2006

I. CALL TO ORDER

Dr. Lorraine Albritton called to order the regular meeting of the Institutional Biosafety Committee. The meeting was called to order at 4:00 p.m. on Friday, September 8, 2006, 910 Madison Ave., Conference Room 801.

II. IBC MEMBERS IN ATTENDANCE

Drs. Lorraine Albritton, Suleiman Bahouth, David Brand, Zheng Fan, Richard Kriwacki, Gary Lindquester, Pat Ryan, William Taylor, Amy Waddell, and Michael Whitt.

III. LIST OF THOSE ABSENT

Dr. Seema Khurana

IV. OTHERS PRESENT

Randall Nelson, Ph.D., Assistant Vice Chancellor for Research

V. APPROVAL OF THE MINUTES

The minutes of August 4, 2006 were presented. Dr. [redacted] made a motion to approve the minutes. Dr. [redacted] seconded the motion. Dr. [redacted] who was not present at the August 4th meeting abstained. The remaining members unanimously approved the minutes as presented.

VI. OLD BUSINESS

None presented.

VII. NEW BUSINESS

Protocol #238

Upon review and discussion, the committee voted full approval of Class IIID BL2 as submitted by investigator. Dr. [redacted] made a motion to approve the protocol as submitted. Dr. [redacted] seconded the motion. All that were present unanimously approved the protocol as submitted.

Protocol #239

The Chair presented protocol #239 for review. Dr. [redacted] informed the committee that she was a collaborator on the protocol; identified investigators response to reviewer's recommendations, and then stated that she felt it appropriate to recluse herself from the meeting to allow the committee to vote. Dr. [redacted] took over as Chair. Upon review and discussion the committee voted full approval of Class IIIE, BL1 and BL2 as submitted by investigator. Dr. [redacted] made a motion to approve the protocol as submitted. Dr. [redacted] seconded the motion. There was a unanimous vote of approval of the protocol as submitted.

Dr. [redacted] resumed her position as Chair. Dr. [redacted] stated that he must leave the meeting, and requested a moment to address the committee. He informed the members of the status of the position for the Institutional Biosafety Officer; stating that a candidate had been selected and an offer is being made. He informed the committee that the Office of Compliance would be re-locating to the 6th floor of the 910 Madison Ave. building which would be a larger facility that would also house the IRB Committee. He detailed facility enhancements that would be put in place to accommodate committee meetings.

Protocol #240

Dr. [redacted] presented background on the agent natalizumab. Upon review and discussion, the committee unanimously agreed that the appropriate notification had been submitted to the IBC for Exempt Status but felt that additional descriptive text on the nature of natalizumab should be added to the protocol for the record. Dr. [redacted] made a motion that the protocol be approved as Exempt. Dr. [redacted] seconded the motion. The remaining committee members were unanimous for a vote of approval to exempt the protocol. Dr. [redacted] excused himself from the meeting.

Protocol #241

After a brief discussion, the committee agreed that the protocol would be held for revision and review. The committee agreed that the investigator would need to address the following: 1) provide a plan for testing for RCR in viral stocks, 2) provide a description and references for the replication competent retrovirus assay, 3) correct a typographical error on page 2 of appendix for RNA labeling, and 4) incorporate relevant information from attachments in either items 7 or 10. Dr. [redacted] made a motion to hold the protocol for revisions and review. Dr. [redacted] seconded the motion. There was a unanimous decision to hold the protocol contingent on revisions and review.

Protocol #237
The Chair informed the committee that the protocol had been reviewed previously and was being reviewed to see if the recommendations had been satisfied. Dr. [redacted] stated that he still could not find justification for the use of separate vectors and stated that the investigator must be more specific in responding when asked for details. Examples were given of how the investigator could satisfy the request, i.e. a statement could read: anything that will produce aerosols i.e. homogenization, pipeting, etc. on things that aren't fixed, would be carried out in a class II biosafety cabinet, "I am using all three vectors because I don't know which one would work best at this time". After further discussion, Dr. [redacted] made the motion to hold the protocol for revisions and review. Dr. [redacted] seconded the motion. All that were present unanimously agreed that the protocol be held for revisions and review. The committee agreed upon review of revisions, the Chair would make the final ruling of approval.

VIII. MISCELLANOUS

Dr. [redacted] made a recommendation to add to the website, instructions to investigators that if they are receiving viral vectors made off-site by another investigator; that they will need to submit a copy of a letter of IBC approval from the supplier's institution along with the protocol. After further discussion and consideration, Dr. [redacted] withdrew her motion and informed the committee that the matter be deferred to the biosafety officer who would soon be brought in who may have experience in this area.

Dr. [redacted] recommended, and the committee agreed, that item 5 on the review/approval request form would be modified to read: "or if human cells will be used at all" you will need to have an IRB approval or an IRB exemption letter.

There was a discussion on the pre-review format that was being used. There were concerns in the timing of communication and exchange of information on protocols from pre-review, to full committee review. After much discussion, Dr. [redacted] recommended the rDNA committee implement a format that proved effective for the Institutional Animal Care and Use Committee (IACUC). Reviewers would be able to access and view protocols files on line that would include reviewer recommendations, and investigator responses prior to full committee review. Dr [redacted] agreed to make the necessary arrangements to put the format in place.

IX. ADJOURNMENT
Dr. Albritton adjourned the meeting at 5:25 p.m.

X. NEXT MEETING
To be held on Friday, October 6, 2006, 4:00 p.m., 910 Madison Ave., Conference Room 801.

Minutes Prepared by: [redacted]
Minutes Reviewed by: Lorraine Albritton, Ph.D., Chair, IBC

/dj