UMBI
UNIVERSITY OF MARYLAND
BIOTECHNOLOGY INSTITUTE

CENTRAL ADMINISTRATION
COLUMBUS CENTER
701 EAST PRATT STREET, SUITE 200
BALTIMORE, MARYLAND 21202
410.385.6300 TEL.
410.385.6331 FAX

March 28, 2007

Edward H. Hammond
Director, the sunshine project
P.O. Box 41987
Austin, TX 78704

Dear Mr. Hammond:

This letter responds to your letter dated October 12, 2006, to the University of Maryland Biotechnology Institute ("UMBI"). Your October 12th letter was a follow-up to an earlier letter dated March 15, 2006, and it reiterated "the Sunshine Project's request for the University of Maryland Biotechnology Institute IBC minutes (from 1 May 2003 through the present.)" I sincerely apologize for the delay in responding to your letter. I have considered your request in accordance with the Maryland Public Information Act, Annotated Code of Maryland, State Government Article, § 10-611 to 628 ("MPIA"). Enclosed, as requested, are copies of the minutes of all UMBI IBC minutes from May 1, 2003, through the present. The date of those meetings were:

June 29, 2004
May 19, 2005
October 17, 2006
November 9, 2006

Limited information has been redacted from these minutes in accordance with §§10-618(d) and (j) of the MPIA, which permit denial of access to documents that contain the specific details of a research project that an institution of the State or of a political subdivision is conducting and records of buildings where hazardous materials are stored.

You may seek administrative review of this decision upon request, in accordance with the MPIA, Annotated Code of Maryland, State Government Article, § 10-622. If requested, such review will be conducted in accordance with State Government Article §§ 10-205 through 221. You may also pursue your judicial enforcement remedies under § 10-623.

Sincerely yours,

Dean Drake
Associate V.P. Research & Development

cc: Carolyn W. Skolnik, Assistant Attorney General

CENTER OF MARINE BIOTECHNOLOGY
University of Maryland Biotechnology Institute
701 East Pratt St., Baltimore, MD 21202

COMB IBC Meeting Minutes
Tuesday June 29, 2004
1:00 to 2:00 p.m.
701 East Pratt Street ([redacted]), [redacted]

Attendees: Feng Chen, Jim Du, Richard Gilpin, Rose Jagus, Kathy Kight, Hal Schreier, John Trant, Rick Tysor, Roy Voelker
Non-attendees: Lisa Gerrity, Fred Paraskevoudaki

Call to order at 1:10 p.m. **Hal Schreier**

New Business: **Hal Schreier/Richard Gilpin**

1) IBC Membership List was revised with minor corrections and will be sent to OBA with each member's curriculum vitae.

2) NIH OBA Submission Requirements, Section IV-B-2 IBC Membership and Procedures were distributed and discussed.

3) Draft COMB IBC Charter was discussed and adopted unanimously.

4) Draft COMB IBC Functions and Tasks were discussed. Paragraph 3 dealing with recombinant plant research was deleted. Paragraph 5 line one, BSL-33 was changed to BSL-3.

   Page two, Paragraph 1 statement about making IBC minutes available to the public contains language taken from the recent statement by OBA on the subject.

   Functions and tasks, with the two changes listed above, were adopted unanimously.

5) Draft Registration of Research with Human Materials, Potential Pathogens, Recombinant DNA and Select Agents (IBC Registration Form) was discussed and modified as follows: Page two, Section E change "IACUC Approval Number" to "COMB IACUC Protocol Number". Page two lower section will eventually be designed to accept cut and paste proposal abstract, specific aims, and methods of procedure (sop's) from word processor programs.

   Members requested an accompanying pdf document be put on the COMB and UMBI R&D websites that describes in more detail the types of research materials that should be registered in Sections A, B, C, and D of the IBC Registration Form.

   The UMBI Routing Form is being revised to reflect a format similar to the COMB IBC Registration Form. Both the Routing Form and the IBC Registration Form will

have yes/no questions dealing with various research materials. The Routing Form will have a line for an IBC registration number, if applicable.

The IBC Registration Form will not circulate with the UMBI Routing Form, but will instead be submitted to the IBC Chair/Biosafety Officer for review, assignment of a registration number, and IBC approval date when appropriate.

The IBC will review proposals requiring a vote on a just-in-time basis. PIs will be requested to submit the IBC Registration Form to the Chair either before or during the time that they submit the UMBI Routing Form to the administration.

The IBC Registration Form, with the one change listed above, was adopted unanimously.

6) The Draft Recombinant DNA Research Memo, Recombinant DNA Annual Update Memo, Human Tissue, Pathogen, or Potentially Pathogenic Material Memo, and the Human Tissue, Pathogen, or Potentially Pathogenic Material Annual Update Memo were reviewed, discussed and adopted unanimously. The IBC Access database and merge memo system will reside in UMBI Research and Development.

Review of proposal(s) **Hal Schreier**

1) No new proposals had been submitted for review.

2) Methods to get proposals submitted to the IBC for review were discussed, including information to be posted at the UMBI R&D website and at the COMB website.

Adjournment at 2:20 p.m. **Hal Schreier**

Minutes062904

UMBI
UNIVERSITY OF MARYLAND
BIOTECHNOLOGY INSTITUTE

Research Compliance, Office of Research & Development
701 East Pratt Street,
Baltimore, MD 21202
Phone: 410-385-6329 Facsimile: 410-385-6346
GILPIN@UMBI.UMD.EDU

MEMORANDUM

TO: Michelle Johnson
IBC Coordinator
National Institutes of Health
Office of Biotechnology Activities
6705 Rockledge Dr., Suite 750
MSC 7985
Bethesda, MD 20892-7985

FROM: Richard W. Gilpin, Ph.D., RBP, CBSP
DATE: July 2, 2004

RE: Center of Marine Biotechnology New IBC Membership

University Members:

Dr. Harold Schreier (IBC Chair Person/BSO)
Associate Professor
Center of Marine Biotechnology
701 East Pratt St,
Baltimore, MD 21202
Phone (410) 234-8874
Fax (410) 234-8896
schreier@umbi.umd.edu

Dr. Richard Gilpin (Contact)
Research Compliance Coordinator
University of Maryland Biotechnology Institute
701 East Pratt St
Baltimore, MD 21202
Phone (410) 385-6329
Fax (410) 385-6346
gilpin@umbi.umd.edu

Dr. Feng Chen
Assistant Professor
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Dr. Rosemary Jagus
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Center of Marine Biotechnology
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Lisa Gerrity (Ex Officio)
Coordinator
Center of Marine Biotechnology
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Phone (410) 234-8802
Fax (410) 234-8896
gerrity@umbi.umd.edu

Dr. John Trant (Animal Expert)
Associate Professor
Center of Marine Biotechnology
701 East Pratt St,
Baltimore, MD 21202
Phone (410) 234-8820
Fax (410) 234-8896
trant@umbi.umd.edu

Richard Tysor (Ex Officio)
Assistant Director
Center of Marine Biotechnology
701 East Pratt St, [redacted]
Baltimore, MD 21202
Phone (410) 234-8805
Fax (410) 234-8896
tysor@umbi.umd.edu

Community Members:

Frederick Paraskevoudakis
Assistant Professor
Department of Biological Sciences
Baltimore City Community College
2901 Liberty Heights Ave
Baltimore, MD 21215
[redacted]
fparaskevoudakis@bccc.edu

Dr. LeRoy Voelker
Sr. Director of Research & Development
Intralytix, Inc.
701 East Pratt St
Baltimore, MD 21202
Phone (410) 625-1224
Fax (410) 625-2506
rvoelker@intralytix.com

Charter
COMB Institutional Biosafety Committee

University of Maryland Biotechnology Institute
Center of Marine Biotechnology
June 2004

Purpose: The purpose of the University of Maryland Biotechnology Institute (University) Center of Marine Biotechnology (COMB) Institutional Biosafety Committee (IBC) is to provide advice and recommendations to the University that will provide for the safe conduct of biomedical research and ensure compliance with local, state and federal requirements.

Membership: The Director of COMB recruits and nominates COMB Institutional Biosafety Committee members. The Office of Research and Development Research Compliance Coordinator shall be a voting member of the committee. Committee members will be drawn from COMB's faculty and staff and the community according to the NIH Recombinant DNA Guidelines. At least two members shall not be affiliated with COMB and will represent the interest of the surrounding community with respect to health and protection of the environment. By virtue of members' participation in the work of the committee, it is expected that the policies developed and recommended to the University will be accepted as binding on the COMB community. Members will serve on the committee for two years and may be appointed for additional terms. The IBC will provide advice on matters related to development of safe biomedical research policies and procedures and approve appropriate research projects.

Chairperson: The chairperson of this committee may administratively approve research protocols without membership majority vote, if IBC voting members do not request committee discussion within ten business days after a protocol is received. Approved protocols will be included in the minutes of the next IBC meeting.

Quorum: A quorum shall exist by or upon a majority of the voting members.

Meetings: Meetings will be held at the call of the chairperson.

Sub-committees: The Institutional Biosafety Committee has authority to appoint subcommittees and ad hoc committees of subject matter experts to address specific issues.

Annual Review and Changes to this Charter: This charter will be reviewed annually. It may be modified or amended by approval of a majority of the voting members.

Functions and Tasks

COMB Institutional Biosafety Committee

University of Maryland Biotechnology Institute
Center of Marine Biotechnology
June 2004

The Center of Marine Biotechnology Institutional Biosafety Committee (IBC) responsibilities are not restricted to recombinant DNA.

The IBC will be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. Membership is outlined in the IBC Charter.

The IBC will include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, require IBC prior approval.

When COMB conducts recombinant DNA research at Biosafety Level Three (BSL-3) or Large Scale (greater than 10 liters), a Biosafety Officer is mandatory and will be a member of the Institutional Biosafety Committee.

In order to ensure the competence necessary to review and approve research involving recombinant R-DNA, pathogens/microorganism, human tissue, or select agents, the IBC will include:

(i) persons with expertise in recombinant DNA technology, biosafety, and physical containment;
(ii) or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and
(iii) at least one member representing the laboratory technical staff.

The UMBI COMB IBC shall file an annual report with the National Institutes of Health/Office of Biotechnology Activities (NIH/OBA) that includes:

(i) a roster of all IBC members clearly indicating the Chair, contact person, Biosafety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise (if applicable) or *ad hoc* consultants, and
(ii) biographical sketches of all IBC members.

No member of the IBC will be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

The UMBI Policies and Procedures Committee may establish procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals, and activities.

Upon request, UMBI shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies that the latter are required to make available to the public. If public comments are made on IBC actions, the institution shall forward both the public

comments and the IBC's response to the Office of Biotechnology Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838.

The University of Maryland Biotechnology Institute shall cooperate with the state and local public health departments by reporting any significant research-related illness or accident that may be hazardous to the public health.

On behalf of the institution, the IBC is responsible for: reviewing research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section IV-B-2, and approving those research projects that are found to conform with the *NIH Guidelines*.

This review shall utilize the UMBI Office of Research and Development routing form submitted with all grant and contract applications, and other requests for extramural support of sponsored programs, and a UMBI IBC research registration form and other materials generated by principal investigators to;

(i) assess the containment levels required by the *NIH Guidelines* for the proposed research

(ii) assess the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research

(iii) ensure that all aspects of Appendix M (if appropriate) are addressed by the Principal Investigator

(iv) ensure that no research participant is enrolled in a human gene transfer experiment until the RAC review process has been completed

(v) evaluate issues raised and recommendations made as a result of a public RAC review and the Principal Investigator's response to RAC comments for human gene transfer protocols and ensure that final IBC approval is granted only after the RAC review process has been completed

(vi) ensure compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*

(vii) provide notification to the Principal Investigator of the results of the IBC's review and approval

(viii) lower biosafety levels for certain experiments as specified in Section III-D-2-a, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*

(ix) set containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*

(x) periodically review recombinant DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*

(xi) adopt emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research

(xii) report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838.

CENTER OF MARINE BIOTECHNOLOGY	UNIVERSITY OF MARYLAND BIOTECHNOLOGY INSTITUTE

REGISTRATION OF RESEARCH WITH HUMAN MATERIALS, POTENTIAL PATHOGENS, RECOMBINANT DNA AND SELECT AGENTS

Send to UMBI Central Administration Office of Research & Development, [redacted]

Questions? Contact IBC Chair, Hal Schreier at (8874) or ORD Compliance Coordinator, Richard Gilpin at (6329)

PRINCIPAL INVESTIGATOR NAME	PROPOSAL NUMBER (Leave blank if not available)
OFFICE MAILING ADDRESS	E-MAIL
PHONE NUMBER	FAX NUMBER
PROPOSAL TITLE	IBC Number (Leave blank)
LABORATORY ROOM ADDRESS(ES)	RESEARCH EMPLOYEE NAME(S)

SECTION A	Yes	No	If No (Go to Section B)
Will the proposal involve human blood or blood components, human tissue culture, or internal body fluid specimens			
Is bloodborne pathogens training complete			
IRB Approval Date			
IRB Approval Number			

SECTION B	Yes	No	If No (Go to Section C)
Will the proposal involve microbial pathogens or potential pathogens			
Genus and species			
Quantity greater than one liter			
Inactivation method			
Concentration method			
Research animals exposed to pathogen			

SECTION C	Yes	No	If No (Go to Section D)
Will the proposal involve recombinant DNA, cloning or formation of transgenic research animals			
E. coli K 12			
Other bacterial genus and species name			
DNA source, genus and species			
Virus vector			
Greater than 2/3 of virus genome			
Virus vector name, source and construct			
Helper virus			
Helper virus vector source and construct			
Plasmid vector source and construct			
R-DNA Host name			
Research animals exposed to R-DNA			

SECTION D	Yes	No	If No (Go to Section E)
Will the proposal involve select biological agents or toxins			

SECTION E	Yes	No	If No (Go to Section F)
Will the proposal involve laboratory animals			
IACUC Approval Number			

SECTION F

Your signature below indicates approval of this proposal and concurrence with the statements of this form.

Principal Investigator: _____ **Date** _____

PASTE INTO THIS DOCUMENT:

Abstract

Methods of procedure

Mitigation of risk to research personnel

Methods used to inactivate microorganisms

COMB IBC Registration Instructions

UMBI procedures require all COMB Principal Investigators register their research with human materials, potential pathogens, recombinant DNA, or select agents with the COMB Institutional Biosafety Committee (IBC). The form "REGISTRATION OF RESEARCH WITH HUMAN MATERIALS, POTENTIAL PATHOGENS, RECOMBINANT DNA AND SELECT AGENTS" is available at the UMBI Research & Development, Sponsored Programs Forms website http://www.umbi.umd.edu/osp/forms.html
Please fill out the rtf form on your monitor screen, save it, and email it to UMBI Research & Development at gilpin@umbi.umd.edu

Human Materials Registration:

Human material(s) to be registered include human tissue samples, blood, serum, plasma, internal body fluids (semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid) and any body fluid that is visibly contaminated with blood) from patients, volunteers, or cadavers as well as human-derived tissue culture cells. Common laboratory cell lines including HEK293 and Hela are not exempt and must be registered. Also included are any unfixed tissue or organ from a human (living or dead), HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV- or HCV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV or HCV.

Pathogens or Potential Pathogens Registration:

Potential pathogen(s) to be registered include all bacterial, viral, fungal, parasitic microorganisms with a potential for vertical or horizontal transmission. Host-specific viruses and viral vectors commonly used for gene transfer must also be registered. This includes, but is not limited to, adenovirus, MuLV, and other commercially available or investigator-generated modified lentiviral and retroviral-based vectors.

Recombinant DNA Registration:

Recombinant DNA to be registered includes all research involving the use or manipulation of recombinant DNA. Recombinant DNA research is defined by the NIH Guidelines [Section IB] as either molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or DNA molecules that result from the replication of molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. Recombinant DNA experiments considered "exempt" as defined within the NIH Guidelines must also be registered.

Select Agent Registration

Select agent(s) to be registered are listed by the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) and include bacteria, viruses, toxins, rickettsia, and fungi that pose a potential threat to public health or welfare. These organisms are considered Select Agents and/or High Consequence Livestock Pathogens and Toxins. Laboratories intending to obtain select agents must be registered with the Centers for Disease Control and Prevention (CDC) through the UMBI Research Compliance Coordinator and must adopt the UMBI Security Policy. Contact Richard Gilpin at 6329 gilpin@umbi.umd.edu

Laboratory Animal Registration

Research with laboratory animals must be coordinated with the COMB IACUC reviewer. Contact John Trant at 8820 trant@umbi.umd.edu

COMB IBC Meeting Minutes
Thursday, May 19, 2005 from 1:00 pm to 2:00 pm
[redacted], Second Floor [redacted]

COMB IBC Members Present			
Hal Schreier Chair	410 234 8874	schreier@umbi.umd.edu	
Feng Chen	410 234 8800	chenf@umbi.umd.edu	
Jim Du	410 234 8854	dus@umbi.umd.edu	
Richard Gilpin	410 385 6329	gilpin@umbi.umd.edu	
Rose Jagus Animal Chair	410 234 8822	jagus@umbi.umd.edu	
Kathy Kight	410 234 8825	kight@umbi.umd.edu	
Fred Paraskevoudaki, Community	410 462-7654	fparaskevoudaki@bccc.edu	
John Trant	410 234 8820	trant@umbi.umd.edu	
Roy Voelker Intralytix, Community	410-625-1224	rvoelker@intralytix.com	
Nanci Henningsen BusMgr, Ex Officio	410 234 8815	henningn@umbi.umd.edu	non-attendee
Rick Tysor Asst Dir, Ex Officio	410 234 8805	tysor@umbi.umd.edu	non-attendee

Old Business: **Hal Schreier/Richard Gilpin**

1) **Minutes of the COMB IBC meeting of 29June 2004 were approved unanimously.**

New Business: **Hal Schreier/Richard Gilpin**

1) Changes in COMB IBC membership accepted include:
   Rosemary Jagus replaces John Trant as aquatic animal expert.
   Nanci Henningsen, COMB Business Manager (Ex Officio) replaces Lisa Gerrity.
2) Revised membership roster will be sent to NIH OBA in June 2005.
3) COMB research laboratory [redacted]protocol registration with UMBI IACUC **Rose Jagus**
   UMBI IACUC website links and forms discussed.
   COMB aquatic [redacted]ubcommittee of the IACUC uses a similar form.
   COMB [redacted]protocols will be voted by the COMB subcommittee membership including three members of the UMBI IACUC.
   Approved protocols will be sent and kept on file at the UMBI IACUC office at the [redacted]

Review of project(s) requiring IBC vote **Hal Schreier**

1) **Prior IBC administratively registered projects by Hal Schreier and Richard Gilpin approved unanimously.**
2) Future reports to the committee will include more detail about biosafety levels, IBC, IRB, and IACUC information, and listing of potentially pathogenic material or pathogens.
3) Current IBC registration memorandum was revised (attached) to reflect more detail.
4) [redacted]itle: EVALUATION OF [redacted] AS A POTENTIAL SINK OR RESERVOIR FOR PATHOGENS AND PARASITES OF [redacted]AND [redacted]
   [redacted]and Pathogen Laboratory and Manual discussed.
   Unanimous vote to place the protocol on hold pending completion of three requirements:
   a) Walk through risk analysis with the PI and committee members to determine laboratory location(s) and containment requirements, and
   b) Satisfactory completion & approval of a Biosafety Manual for the [redacted] & Pathogen Laboratory.
   c) Registration approval from the UMBI IACUC.

Adjourn: 1:59 P.M.

MEMORANDUM

TO: «FSTNAMEPI» «LSTNAMEPI»
Room: «ADDRESS»
Unit: «SECTION»

FROM: Harold Schreier, PhD, IBC Chair
Richard W. Gilpin, PhD, RBP, CBSP, Research Compliance Manager

SUBJECT: IBC Registration of Biological Research.

PROJECT TITLE: «TITLE»

PROPOSAL #: «PROPOSALNO»

IBC REGISTRATION #: «REGISTRNO» **APPROVAL DATE: «IBCAPRDATE»**

NIH GUIDELINE REFERENCE: «RDNASECTION»

POTENTIALLY PATHOGENIC CULTURES OR MATERIAL: «PATHSPP»

BIOSAFETY LEVEL: Facilities «FACBSL»; Practices «PRABSL»

IRB APPROVAL #: «IRBNO» **IRB APPROVAL DATE: «IRBDATE»**

IACUC APPROVAL #: «IACUCNO»

The UMBI ORD has registered your project for the Center of Marine Biotechnology (COMB) Institutional Biosafety Committee (IBC). This memorandum acknowledges your registration in case you need it for your grant application. Please note that each project has a unique IBC Registration Number.

- If you have "Pending" next to the above APPROVAL DATE, you are not approved to begin this research project. You must have an IBC Approval Date before research can begin.
- If the APPROVAL DATE is blank, you do not need approval by IBC vote to begin research.
- This IBC Registration does not replace or IRB and/or IACUC approvals when required.

We will update your project annually. Around the anniversary month of your project registration, we will send you an update letter. Please make any changes to your project, laboratory or office location, changes among personnel, etc., and return the form to ORD.

We will carry out periodic, announced laboratory audits. This will assure compliance with work practices and laboratory facility design appropriate for the level of biosafety assigned to your project.

Please call Hal Schreier at 8874 schreier@umbi.umd.edu or Richard Gilpin at 6329 gilpin@umbi.umd.edu if you have any questions or need additional forms. We look forward to working with you.

RDNAPATH

Minutes of COMB IBC Meeting
Tuesday, October 17, 2006 from 1:00 pm to 2:00 pm
[redacted] 701 East Pratt Street
Second Floor COMB Multipurpose Room [redacted]
Outside Members – Park in Pier 5 Garage Next Door – we pay parking

COMB IBC Membership

Hal Schreier Chair	410 234 8874	schreier@umbi.umd.edu
Feng Chen	410 234 8800	chenf@umbi.umd.edu
Jim Du	410 234 8854	dus@umbi.umd.edu
Richard Gilpin	410 385 6329	gilpin@umbi.umd.edu
Nanci Henningsen	410 234 8815	henningn@umbi.umd.edu
Rose Jagus	410 234 8822	jagus@umbi.umd.edu
Kathy Kight	410 234 8825	kight@umbi.umd.edu
Claudia MacAuley VAMC	410 605 7000 x6544	cmacaule@umaryland.edu
Alexander Sulakvelidze Intralytix	410 625 2533	asulakvelidze@intralytix.com
John Trant	410 234 8820	trant@umbi.umd.edu
Barbara Whipple	410 234 8802	whipple@umbi.umd.edu

Present

Voting

Hal Schreier
Feng Chen
Jim Du
Richard Gilpin
Rose Jagus
Kathy Kight
Claudia MacAuley
Alexander Sulakvelidze
John Trant

NonVoting

Nanci Henningsen
Barbara Whipple

Absent

Voting

0

Excused

0

Total Voting Members: 9otal Voting Attendees: 9 Quorum: 5
Time Started: 1:10 p.m.

Introduction of New Members — Hal Schreier

Nanci Henningsen
Claudia MacAuley
Alexander Sulakvelidze
Barbara Whipple

New members were introduced by the chair and thanked for participating.

Approval of 19May 2005 Minutes (attached)

Minutes of the 19May Meeting approved unanimously.

Old Business: — Hal Schreier/Richard Gilpin

1) COMB research laboratory [redacted] protocol registration with UMBI IACUC and SOP's

Pending COMB items for the UMBI IACUC (below) were discussed. Faculty were asked to pass this information on to other researchers.

Post Meeting Task Summary Updated 28June06: ITEMS 2, 3, AND 11 COMPLETED

a) UMBI IACUC requires one original and 12 copies of applications.
b) UMBI IACUC meetings are held the 4th Friday of every month.
c) Forms should be submitted 7 days before meeting. Renewal forms should be submitted 30 days before expiration date.
d) ORD Compliance waiting for receipt of search terms before exploring databases for aquatic research/
e) COMB PIs will submit IACUC item F Description of [redacted] experimental design and procedures along with grant routing forms. (To be submitted when needed)
f) COMB PIs will update SOPs for all species used and submit to IACUC (Waiting for receipt of SOPs for all species) SOPs for [redacted] done. Working on SOPs for rest of [redacted]

[redacted]

a) Title: EVALUATION OF [redacted] AS A POTENTIAL SINK OR RESERVOIR FOR PATHOGENS AND PARASITES OF [redacted] AND [redacted]
b) IIIF3 R-DNA (Experiments involving DNA from a [redacted] including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
c) DNA from [redacted] and [redacted] transferred into *E. coli* plasmids.
d) BSL-2 Facility, BSL-3 Practices. Endemic, environmentally-acquired pathogens ([redacted] transmission from infected [redacted] to uninfected [redacted] will be studied in closed aquaculture [aquariums with covers in [redacted] Containment Laboratory] by placing potentially pathogenic [redacted] in the aquarium water to infect the [redacted]
e) UMBI IACUC notification recommended

New Business: **Hal Schreier/Richard Gilpin**

1) COMB IBC Annual Report sent to NIH OBA and current committee members received appointment letters from Dr. Zohar on 7Sep06.
The Annual Report was sent to NIH OBA and confirmed by the OBA Director for Institutional Communications.

[redacted]

Adjourn: 2:10 pm

COMB IBC Online Vote Request 9Nov06

Review of project requiring IBC vote [redacted] Vote

Good Morning COMB IBC Members!
We have received another protocol that involves injecting r[redacted]IM into [redacted]o define the types of [redacted]that variable [redacted]can recognize in vivo.
NIH Guidelines Section IIID-4a (R-DNA from any source except for greater than two-thirds of eukaryotic viral genome transferred to any [redacted] [redacted]BSL-1) requires an IBC vote.
Your vote is due by COB on Monday, November 23, 2006.
Review the attached documents and my comments below and vote by email...
1) Yes
2) No
3) Abstain/more information needed
4) If any member wishes to have a formal meeting to discuss the protocol please contact me or Hal Schreier as soon as possible.
My comments:
[redacted]
Title: Antigen recognition by variable lymphocyte receptors (VLR)
[redacted]
Plasmid DNA fragments from E. coli with M13 phage construct will be cloned and injected into [redacted]VLR cDNA libraries will be generated by RT-PCR from transcripts derived from blood buffy coat lymphocytes. Restriction sites will involve cloning into the [redacted] and also in the [redacted]nd the [redacted]expression vector.
BSL-1 facilities and practices.
I recommend approval.
Richard W. Gilpin, Ph.D., RBP, CBSP

Vote to Approve
Hal Schreier
Richard Gilpin
Rose Jagus
Kathy Kight
Claudia MacAuley
Alexander Sulakvelidze
John Trant
Vote to Not Approve
None
Not Voting
Feng Chen
Jim Du
Total Voting Members: 9 Total Voting Yes: 7 Quorum: 5
Motion to approve protocol passed .