

Envelope-to: hammond@sunshine-project.org
Date: Mon, 20 Mar 2006 15:24:11 -0500
From: Yvonne Glendon <yvonne.glendon@tufts.edu>
Organization: Tufts University
X-Accept-Language: en-us, en
To: Edward Hammond <hammond@sunshine-project.org>
Subject: As requested by your FACIMILE

Hello Ed,
Two years ago, I believe that I sent the information you requested via e-mail attachment.
It worked out well then, so here is the information requested via your recent FAX.

By the way, as you will note in my cover letter attached, the request was received last week, either on Thursday or Friday, and was then re-directed to my office on Friday afternoon at 2:04 PM.

I was on vacation on Friday, March 17th, and did not receive the fax information until this morning.

Attached, you will find Minutes of all meetings since May 1 of 2003.

If you need anything further, please do not hesitate to give me a call or e-mail.

Thanks
Yvonne Glendon
Biosafety Manager
TEL = 617-636-2919
FAX = 617-636-2419

Attachment converted: New Fish:Response letter and #4F86BC.doc
(WDBN/«IC») (004F86BC)
Attachment converted: New Fish:IBC minutes 3-22-05 #4F86C8.doc
(WDBN/«IC») (004F86C8)
Attachment converted: New Fish:IBC minutes 8-5-04 -#4F86D0.doc
(WDBN/«IC») (004F86D0)
Attachment converted: New Fish:IBC minutes 9-22-03 #4F86D5.doc
(WDBN/«IC») (004F86D5)
Attachment converted: New Fish:IBC minutes 10-3-05 #4F86D8.doc
(WDBN/«IC») (004F86D8)



TUFTS/NEMC

INSTITUTIONAL BIOSAFETY COMMITTEE

Meeting Minutes

September 22, 2003

Members Present: Drs. Cheleste Thorpe, Joseph Alroy, Jeanne Fahey, Jeanne Fahey, David Lazinski, Victoria Mellor, Matt Waldor, Mss. Yvonne M. Glendon, Rosemarie Van Camp,

Members Excused: Drs. Douglas Jefferson, Daniel Liberman, Ms. Karen Rose

Guests: Robert Burgess, CHEM, Environmental Health Officer for NEMC
Peggy Newell, J.D., Associate Provost for Research – Tufts University

Call to order:
Dr. Cheleste Thorpe called the meeting to order at 12:15 PM.

I. Old Business

- A. **Review of Minutes** –Minutes from the previous meeting were approved unanimously and signed by Dr. Thorpe.
- B. **Grafton Infectious Disease/Employee Illness Update** – Ms. Glendon provided the committee with an update on employee illness occurrences in the Division of Infectious Disease. Certain recommendations made by outside consultant group from Yale were discussed, including:
 - 1. Environmental microbiological sampling is being done in both the calf and piglet containment rooms, swabbing environmental surfaces which would be expected to be found clean. Samples are submitted to Biotech testing services for analysis of presence of marker pathogens. Sampling is done after protocol has ended and suite has been decontaminated according to standard protocol.

Also, sampling is done while projects are ongoing, but samples are taken only in the entry vestibule, which should remain clean, assuming people are doing what they are supposed to, to prevent environmental contamination. Dr. Alroy inquired as to the results, Ms. Glendon responded that thus far all cultures have been negative. Sampling has been done 2 times per month. Ms. Glendon offered that perhaps the sampling could be done less frequently. Ms. Newell offered that testing should not be reduced to less than once per month.

2. Plans in the works for persons to be hired to work within the Division of Infectious disease will undergo a pre-employment physical and health risk assessment. Candidates will receive counseling on hazards to immune compromised persons working in this area. Physicians will then make the determination based on medical findings and associated risks, if person can be cleared for work in this area.
3. Employees are also now required to submit a sample to the Fallon Health group. Only three occasions were subsequently noted in which employees developed diarrhea which was thought to be associated from work. These samples were submitted to Fallon, and all three were found to be not associated with the species and type which are investigated at Tufts. Employee sick time, as a result of this plan, appears to have diminished in this division.

II. New Business

A. Update on Current Status of Tufts University Select Agent Registration

Ms. Glendon reported to the committee that registrations for Select Agent work had been submitted to the CDC/Select Agent Program in mid February 2003 for each campus, obtaining accession numbers # 001, 002, and 003 respectively. CDC evaluated the registrations, Medford was working with non-reportable quantities of Botulinum toxin, Grafton's registration was denied because the construction completion was too far in the future and we were told to re-submit. In Boston, researchers using Yersinia pestis, attenuated strains, Ms. Glendon was told this registration was necessary as it had not yet been exempted. Registration papers were drawn up and submitted to CDC. Two days later the strain was listed on the exempt list.

Ms. Glendon reported that subsequently the CDC asked her to send certified letters to the SAP requesting that the registrations be rescinded. This effectively retires accession numbers # 1, 2 and 3 from 'active duty'.

Ms. Glendon continued that she continues to work on the background work in order to have everything in order for when the BL-3 suite comes closer to completion and a new registration can be submitted. 1) Fingerprints have been taken and submitted to FBI, of Nicholas Magliano, Alternate Responsible Official and Yvonne Glendon, Responsible Official. 2) CDC notified of persons at Tufts who have 'control' over the BL-3 space, such as the Chair of the department, the Dean, Saul Tzipori, and even President Bacow.

Ms. Glendon reported that her original set of fingerprints were smudged and that the FBI

requested a second set. After speaking with the FBI on 9/18/03, it was discovered that even the second set of prints had problems. It was deduced that due to the RO's age and leisure time activities such as gardening, sanding furniture etc., that her fingerprints had in fact begun to wear off. The FBI was able to combine the two sets and arrive at a complete set of acceptable prints for Ms. Glendon.

B. Robert Burgess, - Update on Select Agent Regulations

Environmental Health Officer – NEMC, Robert Burgess, was introduced to the committee members.

Mr. Burgess reported that when he arrived as a new employee for NEMC, he found that they were severely under the gun as far as submitting a registration. Bob continued that one of his findings was that while people were working with Select Agents, all were working with amounts that classified them as exempt from the rule. He reported that similar to Ms. Glendon's case, the CDC requested the NEMC's application be withdrawn.

Dr. Cheleste Thorpe, Chair of the IBC offered an explanation of some concerns regarding those folks who are working with Shiga toxin producing strains of E. coli. Dr. Thorpe explained the issues surrounding application for an RO1 grant, and concerns of why NEMC had not registered with SAP. CDC explained that some STech strains are considered reportable, some are not. Subsequently, Dr. Thorpe attempted to import certain strains of the E. coli since the 26th of August. She had to complete an informative letter stating that the strains that were being imported would not be used to make toxin. Dr. Thorpe felt that the Import/Export agency was uncertain of how to proceed, and this uncertainty filters down to the applicant. Approvals are supposed to be completed in two weeks, and Dr. Thorpe's application has been well over two weeks.

Dr. Thorpe also questioned if she tried to register the strains which are exempt, stating MIT as an example, are they allowed to register these strains? Bob Burgess added that to the best of his information, some have attempted to register, these have been bounced back by SAP because low levels of the agents or what not. He felt that there may be some amount of disconnect among certain groups, and that everyone is trying to err on the side of caution. Dr. Thorpe stated that they may try to register, it will be a tremendous amount of work and then they too will get a "don't bother us" response from SAP. Dr. Thorpe continued that if anyone over at Tufts was contemplating working with any of the agents that it would take a tremendous amount of time. Ms. Glendon offered that she did not know presently of anyone new planning to do such work on the Boston Campus. Dr. Thorpe added that she was aware that NEMC was building a BL-3 suite for Dr. Wei Chun Goh. Ms. Glendon offered that currently Wei Chun was using the BL-3 suite in Dr. Coffin's lab, since this area had been certified to be within compliance for operations of a BL-3 suite, to which Dr. Thorpe responded that she could not use it because there was not the proper equipment. Dr. Thorpe added that Dr. Goh had been here for 6 months and had not yet been able to do any of her virology. This can be quite serious for a scientist's career, to experience such delays. Dr. Matt Waldor addressed the issue stating his not being fully understanding of the issue. He understood that there appears to be a situation where two branches of the government are not talking to each other. Further, he stated that it was his understanding that the materials with

which he was working did not need a special license. **Dr. Thorpe** responded to this that that was her understanding also. **Ms. Glendon** offered that it had been her experience that when one called the SAP program at CDC, one did not get to speak to someone directly, rather are directed to leave a message and someone will call back, adding that they would not respond to anything in writing, only verbally, not sending anything in writing. There is conflicting information given out and overall it is a very frustrating experience. **Ms. Glendon** suggested that it most likely is a frustrating situation for folks at SAP also. This program is a huge undertaking, created or modified, post 9-11, and rapidly, without the necessary infrastructure to support it. **Dr. Alroy** added that without proper leadership on site, things would be difficult and decisions slow in the making. **Dr. Thorpe** continued that she will continue to do her work, and if Dr. Waldor is told that he too needs to be registered, and then NEMC will need to go through the process. **Mr. Burgess** added that perhaps one should go through the process and if rejected by CDC they would at least then have the letter stating that they did not need to register.

Mr. Burgess explained that although NEMC had been told by CDC that they did not have to register, he received a call from an inspector saying that he needed to schedule a time to come and inspect the laboratory. When Mr. Burgess informed the inspector that he had been told by CDC that they need not register, the inspector was surprised to hear that. Apparently although an entity may be taken off one list, they remain on other lists for scheduling inspections, etc.

C. Update on BL-3 Laboratories in Boston & Construction of one Suite in Grafton

BL-3 suite in Dr. Huber's lab is functioning, as well as Dr. Coffin's lab. The fact that they are not currently being used as BL-3 units lies more with lack of equipment than anything else. The suite in Grafton is slated for late January, early February completion. At which point Select Agent registration process can be initiated, including application for the Botox grant studies. **Ms. Glendon** asked if there were any questions on the BL-3 suites. **Dr. Thorpe** inquired about use of the BL-3 suite at NEMC, to which **Mr. Burgess** replied he was not certain.

D. Other New Business

Ms. Glendon advised the committee of the story of "Lilly" the white boxer puppy who was admitted to Tufts Grafton SAH 2 month old dog. Was in hospital less than 48 hour when she expired. Differential diagnosis of rabies was not even considered until close to the end of the time shortly before she died. Statistics on contact 68 contact, 21 students, 47 employees, 5 persons elected to go to their own physician, 11 determined to have no exposure and will receive no treatment. Of 21 students, they were still trying to contact 2 students (all have now been contacted) and a few employees still trying to track down. Seven persons previously unvaccinated and are receiving the full vaccine regimen 5 shots, may also be getting the HRIG (human rabies immune globulin) 6 shots all together. **Dr. Thorpe** offered that is was many many more than just 6 shots, that the HRIG was very dilute and given in multiple injections at the exposure site. Tufts was fortunate that Fallon had the serum in their freezer. Fallon also responded immediately and set up a clinic on site at Tufts to do the vaccinations the very next day. They then made arrangements for those receiving the full set to go to Fallon for days 7, 14 and 28. First two shots were done right at the campus. **Ms. Van Camp** inquired if that was all the people that were exposed. **Ms. Glendon** responded that these were just the Tufts people,

students, faculty and staff that were in question. The Public Health had been contacted by Tufts, who then notified the public via television and newsprint of the possible human exposure.

Ms. Glendon continued, explaining that the mother of the puppies and her litter were sometimes housed outside in a fence enclosed pen. DPH worked with the owner of the bitch, identifying those individuals who purchased puppies. One new owner contacted Tufts and stated that since he felt that the risk was too great, requested to come in and have the puppy euthanized. **Ms. Van Camp** inquired about the persons who were exposed to the puppy on the Nantucket ferry. **Ms. Glendon** answered that those people were not Tufts responsibility.

Peggy Newell and **Ms. Van Camp** inquired if **Ms. Glendon** knew anything about these other people and if they had been identified or treated. **Ms. Glendon** responded in the negative, that only that it had been advertised warning any persons who had taken that ferry and had contact with the white boxer puppy needed to contact DPH. **Dr. Thorpe** added information about a baby bear in a petting zoo in the mid-west who, it was estimated, had contact with over 800 children.

Dr. Thorpe inquired about the 11 people who had not previously been immunized, were they people who perhaps 'should' have been pre-immunized? **Dr. Alroy** feels that it should be compulsory. **Ms. Glendon** responded in a manner to explain she had previously attempted to change the current policy of rabies vaccination. Which is: Vet students- must be vaccinated, Wildlife employees- must be vaccinated, other than that, other positions, which involve work with susceptible species- it is strongly recommended that they receive the rabies vaccine. **Dr. Thorpe** suggested that as a result of this incident, Tufts may want to take an evaluation look at expenses incurred, and make plans to change their policy, since we know that this type of thing happens. HRIG is so expensive, it may be more cost effective to pre-exposure immunize. **Ms. Glendon** added that several years ago she had collaborated with the medical director, Dr. Jim Ross, of the SAH, requesting just that, and Dr. Ross was able to add rabies vaccination to be available on a "covered" basis for at risk employees. **Dr. Thorpe** applauded this action, citing the cost savings and also the elimination of the need to give post exposure HRIG, which carries the added risk of use of human products in other humans.

Dr. Alroy added that this was not the first time that they had a rabies case in the hospital. **Dr. Alroy** had already been vaccinated, and this was the main reason why he had decided to only check his titer. **Ms. Glendon** added that even though one had been previously vaccinated and had a protective titer, MDPH still recommended post exposure 2 shots. **Ms. Glendon** gently reminded **Dr. Alroy** that regardless of a protective titer, he should obtain the two post exposure shots, ASAP.

III. New Protocols

A. rDNA Protocols

Ms. Glendon reminded the committee that Dr. Hu's protocols, 2003-003 (rDNA) and 007-2003 (Infectious agent) using vaccinia virus as a vector had been distributed to the committee during the interim between meetings, and that an approval had been voted upon.

Protocols #'d 2003-001 through 2003-042, which were administratively approved by the Biosafety Officer, were reviewed and approved unanimously by the committee.

B. Infectious Agent Protocols

Protocols #'d 001-2003 through 057-2003, which had been administratively approved by the Biosafety Officer, were reviewed and approved unanimously by the committee.

C. **Ms. Glendon** reminded the committee that all protocols except for Dr. Hu's had been administratively approve by her in the intervening time since the last meeting. **Ms. Glendon** asked for a motion to give full committee approval for the protocols. **Dr. Alroy** made the motion and it was seconded by **Ms. Rosemarie VanCamp**. The motion was approved unanimously.

IV. Other Business

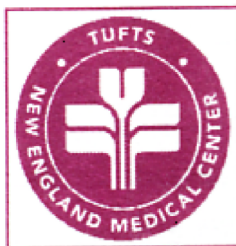
There was no other business to discuss. The meeting was adjourned by Dr. Thorpe at 1:30 PM.

Approval of Minutes:

(As of yet, 5-27-04, unsigned. IBC Chair is on Maternity leave)

Cheleste Thorpe, MD, Chair Institutional Biosafety Committee

Date



**TUFTS/NEMC
INSTITUTIONAL BIOSAFETY COMMITTEE
Meeting Minutes
August 5, 2004**

Members Present:

Dr. Cheleste Thorpe, Committee Chair, Joseph Alroy, DVM, Jeanne Fahey, Ph.D., Yvonne Glendon, MS, RBP Committee Administrator, David Lazinski, Ph.D., Kirk Martin, CBSP, Assistant Biosafety Officer-Grafton, Karen Rose, R.N., Eli C. Siegel, Ph.D., Sam R. Telford, III, Sc. D, Rosemarie Van Camp, Community Representative, Dr. Matthew Waldor

Guests:

Peggy Newell, J.D., Vice Provost, William New, VP., Research Administration-Tufts-NEMC, Robert Burgess, Jr. CHEM, Envir. Health Manager – Tufts-NEMC, Jean Mukherjee, DVM, Ph.D.

Call to order:

Dr. Thorpe called the meeting to order at 12:30 PM.

I. Introduction of New Members

- a) **Drs. Eli Siegel, and Sam Telford were introduced as new members to the committee.**
- b) **Round table introductions made by each member for benefit of the new members.**

II. Old Business

- a) **Review of Minutes from previous meeting, September 22, 2003. The minutes were reviewed and approved unanimously by the committee and signed by Dr. Thorpe.**
- b) **Ms. Glendon gave an update on the progress towards CDC registration for work with Select Agents. The CDC Select Agent program inspectors are due to visit the facilities in Grafton on September 23rd. There have been significant setbacks in the construction of the BL-3 suite, due to architect and engineer miscommunication regarding type of BSC, and needed duct specifications for proper operation. We are concerned that these setbacks will have significant impact on our final approval.**

III. New Business

- c) **Dr. Thorpe discussed the issues surrounding infectious agent registration # 009-2004 PANCAC-V – BL-2 and PANVAC-F – BL-1, and rDNA # 2004-019 – TBC-PAN-003 A Phase III randomized, controlled study to evaluate the Safety & Efficacy of PANCAC™-VF in combination with GM-CSF Versus Best Supportive Care of Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas who have failed a gemcitalbine-containing chemotherapy regimen – BL-2.**
 - a. **There were concerns about how to handle the trash associated with the project, the dressings, etc. Mr. Burgess was to work with Dr. Talavera to create an SOP for infection control management.**
 - b. **It was determined that all protocols involving humans should be reviewed by the full committee, regardless of Biosafety Level.**
- d) **Update/Tour (visual) of the BL-3 and BL-2 Select Agent Suites in Grafton**
- e) **A visual tour was given, and further discussions of construction woes and CDC certification concerns.**

- f) **Change of Duties for the IBC Oversight**
 - a. Ms. Glendon suggested that since CDC approval for work with Select Agents would most likely be given, that such work, with the infectious agents AND toxins would need to be considered by the full committee. Review of Toxin registrations would be a new area of responsibility for the committee, but would be limited only to those toxins that are considered to be Select Agents.
- g) **Other New Business**
 - a. The committee discussed the possibility of creating a new protocol form including both infectious agent and rDNA safety registrations, possibly toxins as well. In addition, there was discussion on creation of a BL-3 specific safety registration. Ms. Glendon and Mr. Kirk Martin will begin the evaluation and design.

III. New Protocols

- a) Talavera # 2004-019, and 009-2004– discussed at the outset of the meeting, see above
- b) **Infectious Agent # 021-2004 – Sam R. Telford, III, Sc.D., F. tularensis tularensis, F. tularensis holarctica – BL-3 and F. philomiragia, F. novicida – BL-2. USE OF SELECT AGENTS.** Dr. Telford was on hand to give a detailed report of the work that he has been doing, and to answer any questions that the committee had. The committee had been given the protocol prior to the meeting. Protocol was approved unanimously. No follow up was needed.
- c) **Infectious Agent # 022-2004 – Botulinum-neurotoxin producing strains of Clostridium sp., including, but not limited to: C. Botulinum, C. butyricum, and C. baratti – BL-2, USE OF SELECT AGENTS.,** Dr. Jean Mukherjee, principal investigator for this work was on hand to discuss this work. Committee had many questions, see below, in discussion of work with the toxin. This Protocol was approved unanimously
Carcinogen/Biohazard/Toxin # 2004-49CB USE OF SELECT AGENTS. Activities with this And other agents is strictly controlled by the CDC Select Agent program. Protocol was approved unanimously with conditions that concerns below were addressed. See discussion below. rDNA protocol # 2004-030 Saul Tzipori/Jean Mukherjee, rDNA Techniques relating to Botulinum toxin producing strains of C. Botulinum and EHEC – BL-2 (Select Agent) All of above protocols in subsection “c” were approved unanimously
 - a. Committee had concerns of availability of the IND vaccine for Botulinum toxin. This vaccine, as explained by Dr. Mukherjee, is not efficacious for all strains of the toxin, and may not be fully protective should there be an exposure.
 - b. Committee had concerns of the availability of the anti-toxin from the CDC should there be an exposure, and the rapidity of their response time. A sub-committee was formed to meet at a later date to discuss issues of acquisition of anti-toxin, education of staff working with the toxin, setting up a vaccination program via Tufts-NEMC, should one be needed, who would do this, and what, if any, anti-toxin was available from the local area public health “push packs” that are distributed throughout the US for rapid response to bioterror attack.
 - c. Committee discussed the possibility of political action to get a dose of Botox antitoxin released for storage and immediate use on site.
 - d. Committee recommended that a protocol be created that can be provided to UMass medical ER Physicians, which would include the emergency number to contact CDC for obtaining the antitoxin. This protocol would be brought with the exposed person to the hospital. The hospital would also previously have a copy and be familiar with the protocol.

IV. rDNA Protocols – All previously administratively approved registrations were approved unanimously by the committee.

2003-043	Barleu, Nicolai	MORI	The Role of a New Human Transcriptional adaptor, Ada2beta, in regulation of p5B-dependent transcription – BL-1
2003-044	Hinds, Philip W	MORI	The Retinoblastoma Protein Pathway in Differentiation, Senescence and Cancer – BL-2
2003-045	Bohm, Alex Andrew	Biochemistry –	Mechanism of Poly(A) Polymerase Processivity – BL-1
2003-046	Meiri, Karina	Anatomy & Cell Biology –	Signal Transduction in the Neuronal Growth Cone – BL-1/ BL-2
2003-047	Widmer, Giovanni	Biomedical Sciences –	Molecular Biology of Enteric Protozoan Parasites – BL-2
2003-048	Hu, Linden	GioMed/ID	Pathogenesis of Lyme Arthritis
2003-049	Du, Keyong	MCRI – NEMC	Regulation of Metabolism by Aclp – BL-2
2003-050	Park, Ho-Jin	MCRI – NEMC	Role of Sterls in the Regulation of Cardiac Autonomic Genes and Angiogenesis – BL-2
2003-051	Cochran, Brent	Physiology	Regulation of Cell Growth – BL-2
2003-052	Lemire, Joan M.	Anatomy & Cell Biology	Decorin Deficiency in Hutchinson-Gilford Progeria – BL-2
2003-053	Gordon, Leslie B.	Anatomy & Cellular Biology	Differential Effects of Progerin Expression on Human Cellular phenotypes in \Hutchinson Gilford Progeria Syndrome – BL-2
2003-054	Watnick, Paula	Geographic Med	Influence of the environment on Vibrio cholerae infectivity & biofilm development – BL-2
2003-055	Skelly, Patrick	Biomedical Sciences	Schistosome surface proteins as protective vaccines against schistosomiasis – BL-2
2003-056	Xu, Zhenkang	Env. & Population Health	Peabody Pavillion – Effects of Cadmium on biology and gene expression shrimp postlarvae – BL-1
2004-001	Herman, John E.	Div. Inf. Disease	Cancer Immunotherapy – BL – 1
2004-002	Kaplan, David L.	Biomed. Eng.	Production of Conjugated Shigella-Antigen Vaccine – BL-1
2004-003	Huber, Brigitte	Pathology	Cleavage of Gut Peptide Hormones by QPP/DPP2 – BL-1→2
2004-004	Kuperwasser, Charlotte	Physiology	Molecular and Cellular Interactions in Breast Tumorigenesis & metastasis – BL-2
2004-005	Liscum, Laura	Physiology	Analysis of intracellular cholesterol transport - BL-1
2004-006	Azuma, Chieko	Oncology – TUSVM	ID of therapeutics that can positively influence radiotherapy of solid vascularized tumors by elevating intracellular levels of the apoptosis inducer, ceramide, in tumor endothelial cells - BL-2
2004-007	Blaustein, Robert	MCRI	Conformational changes associated with K ⁺ - BL-2

2004-008	Sonenshein, Abraham Microbiology	
	Toxin synthesis and sporulation in <i>Clostridium difficile</i>	BL-2
2004-009	Hu, Linden Geomed/ID	
	Peptide transport and signaling in <i>Borrelia burgdorferi</i>	BL-2
2004-010	Cox, Daniel MCRI	
	Regulation of BL Channel Gating by its Beta Subunit	BL-1
2004-011	Geck, Peter Anatomy	
	Estrogen-Induced Molecular Mediators of Breast Tumor Regression	– BL-1
2004-012	Sonenshein, Abraham Molecular Biology	
	The cod Y gene of the <i>Bacillus anthracis</i> Sterne strain	– BL-2
2004-013	Meller, Victoria Biology	
	The molecular genetics of dosage compensation in <i>Drosophila</i>	– BL-1
2004-014	Rios, Maribel Neuroscience –	
	Regulation of Energy Balance and Behavior by BDNF	– BL-2
2004-015	Force, Thomas MCRI –	
	Cytosolic phospholipase A2 and cardiac hypertrophy	– BL-1
2004-016	Vetter, Douglas Neuroscience –	
	Mechanisms of Auditory Processing	– BL-1
2004-017	Arias, Irwin Physiology –	
	Effects of Dominate Negative Rab Constructs on Bile Transport and Secretion	– BL-2
2004-018	Force, Thomas MCRI –	
	Signaling Mechanisms Governing Cardiac Hypertrophy	– BL-2
(***2004-019	Talavera, Joyce R. Heme/Onc –	
	Evaluation of the safety & efficacy of PANVAC TM -VF in combination with GM-CSF versus Best Supportive Care or Palliative chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas who have failed a Gemcitabine-Containing Chemotherapy Regimin	– BL-2 Discussed at length at the meeting by Dr. Thorpe and the committee. See preceeding notations.
2004-020	Garlick, Jonathan A. Oral/Dental Pathology	
	Stem Cells for Oral Mucosal Replacement Therapy	– BL-2
2004-021	Gordon, Leslie Anatomy	
	The Effects of Altered Lamin A on Disease Process in Hutchinson-Gilford Progeria Syndrome	BL-2
2004-022	Feig, Larry Biochemistry	
	Function of Ras Related RAL Proteins	– BL-2
2004-023	Ivaw,Mircea MORI	
	Functional Interactions and Regulation of Oxygen Sensing Hydroxylases	BL-2
2004-024	Shirihai, Orian Pharmacology	
	Silencing, inactivation and overexpresssion of ABCme	– BL-2
2004-024	Waldor, Matthew MBM	
	Shiga toxin-producing <i>E. coli</i> pathogenesis in infant rabbits	– BL-2
2004-025	Baba, Timothy Pediatrics	
	Phage Display Technology in AIDS Vaccine Design	– BL-2
2004-026	Lamon-Fava, Stefania Lipid Metabolism Lab	
	Nutritional Regulation of Reverse Cholesterol Pathway	– BL-1
2004-027	Poltorak, Alexander Pathology Department	
	Genetic Studies of LPS Response	– BL-1
2004-028	Kaplan, David L. Biomedical Engineering	
	Inhibiting Barnacle Surface Interactions	– BL-1

2004-029 Bullock, Peter A. Biochemistry
 Studies of the Initiation of SV40 DNA Synthesis in Vitro – BL-1
 2004-030 Mukherjee, Jean Biomedical Sciences
 rDNA Techniques relating to Botulinum toxin producing strains of C. Botulinum
 and EHEC – BL-2 **(Select Agent)**

V. Infectious Agent Registrations – All previously administratively approved registrations were approved unanimously by the committee.

058-2003 Meydani, Simin N Nutritional Immunology Lab
 HNRCA -
 Cocksackievirus B3(CVB3/0) – BL –2
 059-2003 Van Etten, Richard MORI
 Replication defective ecotropic murine retrovirus – BL-1
 060-2003 Brown, David W Biomedical Sciences
 Hepatitis C virus – BL-2
 061-2003 Chin, Kevin Hematology/Oncology
 Human tissues – possible pathogens – BL-2
 062-2003 Maffini, Maricel Anatomy & Cell Biology
 Rat mammary tissue & primary cell cultures – BL-1
 063-2003 Rosenberg, Ph.D. Pathology
 Abelson murine leukemia virus, Moloney murine leukemia virus – BL-1
 064-2003 Meiri, Karina Anatomy & Cell Biology
 Replication-incompetent Moloney murine leukemia virus – BL-1
 065-2003 Perrin, Mercio Pathology
 Trypanosoma cruzi, Leishmania major – BL-2
 066-2003 Skelly, Patrick J. Biomedical Sciences
 Schistosoma mansoni – BL-2
 067-2003 Gordon, Leslie Beth Anatomy & Cellular Biology
 Human cultured cells – (lymphoblasts, fibroblasts, smooth muscle cells, and
 endothelial cells) – BL-2
 068-2003 White, Alexander C. Pulmonary & Critical Care – NEMC
 Human source materials – BL-2
 069-2003 Hu, Linden Geomed/ID
 Human Adenovirus (replication deficient adenovirus) – BL-2
 070-2003 Park, Ho-Jin MCRI
 Avian RCAS virus BL-1, Adenovirus BL-2
 071-2003 Cochran, Brent Physiology
 Adenovirus 5 (E1a deficient)
 001-2004 Schaffhausen, Brian Biochemistry
 Human HUVEC cells – BL-2
 002-2004 Telford, Sam Biomedical Sciences
 Deer tick-transmitted infections (Lyme disease, granulocytic ehrlichiosis, babesiosis)
 and tularemia vaccine strain LVS – BL-2
 003-2004 Sonenshein, Abraham Molecular Biology
 Bacillus anthracis Sterne strain – BL-2
 004-2004 Roy, Ananda Immunology
 VSVG viral envelope – BL-2+
 005-2004 Beasley, Debbie MCRI - Tupper 222
 Chlamydia pneumoniae – BL-2
 006-2004 Rios, Maribel Neuroscience

	HSV gfpcre and HSVgfp viruses – BL-2	
	MSCV-GFP - BL-2	
007-2004	Beasley, Debbie	MCRI –
	Recombinant replication-deficient adenovirus type 5 (rAd5) – BL-2	
008-2004	Arias, Irwin	Physiology –
	Replication deficient Adenovirus – BL-2	
(***009-2004	Talavera, Joyce	Heme/Onc
	PANVAC-V (recombinant vaccinia – BL-2	
	PANVAC-F (fowlpox virus) – BL-1	
010-2004	Garlick, Jonathan A.	Oral Pathology
	Recombinant Retroviral Vector – BL-2	
011-2004	Wood, Richard J.	HNRCA
	Mineral Bioavailability Lab	
	pSUPER.retro.neo ⁺ gfp Vector System for Expression of Short Interfering RNA BL-2	
012-2004	Surks, Howard K.	MCRI
	750 Washington Street Tupper 12 Box 80	
	Replication-defective lentivirus for expression of Small interfering RNA – BL-2	
013-2004	Georgescu, Serban	MCRI
	Tupper 12	
	Recombinant, replication-deficient adenovirus – BL-2	
014-2004	Mukherjee, Jean	Biomedical Sciences
		All below at BL-2

Actinobacillus lignieresii
Actinobacillus pleuropneumoniae
Actinobacillus suis
Actinomyces bovis
Actinomyces pyogenes
Bacillus cereus
Bacillus licheniformis
Bacillus subtilis
Bacteroides melaninogenicus
Bordetella bronchiseptica
Clostridium difficile
Clostridium perfringens
Corynebacterium pseudotuberculosis
Enterococcus faecalis
Erysipelothrix rhusiopathiae
Excherichia coli
Klebsiella pneumoniae
Mannheimia (Pasteurella) hemolytica
Moraxella bovis
Nocardia sp.
Pasteurella multocida
Proteus mirabilis

Pseudomonas aeruginosa
Rhodococcus equi
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus hyicus
Staphylococcus intermedius
Streptococcus agalactiae
Streptococcus bovis
Streptococcus equi
Streptococcus pyogenes
Alternaria sp.
Aspergillus fumigatus
Candida albicans
Cryptococcus neoformans
Fusarium sp.
Malassezia furfur
Microsporum canis
Microsporum gypseum
Trichopyton mentagrophytes
Trichophyton rubrum
Trichophyton terrestre
Trichophyton verrocosum

015-2004	Almedom, Astier M.	Biology Dept.
	Sterilized Human saliva samples	BL-2 → BL-1
016-2004	Waldor, Matthew	MBM
	Shiga Toxin-producing E. Coli – BL-2	
017-2004	Shirihai, Orian	Pharmacology

	Lentivirus – HIV derived – BL-2	
018-2004	Isberg, Ralph R.	Microbiology
	Legionella pneumophila – BL-2	
019-2004	Adams, Sharlene	Point Therapeutics
	Human tumor cell line “Raji” from ATCC	
	Other Human tumor cell lines: Caco-2, CAL 27, FaDu, MIA PaCa-2, BxPC-3, PANC-1, MeWo, A2058, A-375, SK-MEL-28, A549, NCI-H460, SK-ES-1, HT-1080, MG-63, SW-620 and MNNG/HOS – All at BL-2	
020-2004	Adams, Sharlene	Point Therapeutics
	Mouse Tumor cell lines, CT26.WT and CT26.CL25 – BL-1	
(***)021-2004	Telford, Sam R.	Biomedical Sciences
	Francisella tularensis tularensis, F. tularensis holarctica – BL-3	
	F. philomiragia, F. novicida – BL-2	
(***)022-2004	Mukherjee, Jean	Biomedical Sciences
	Clostridium botulinum (neurotoxin producing) – BL-2	
023-2004	Wood, Richard J.	HNRCA Mineral Bioavailability Laboratory
	pLenti4.F:AG.CaT1.EGFP viral vector	BL-2
	293FT viral packaging cells	BL-2
024-2004	Kuperwasser, Charlotte	Physiology
	Human breast and bone tissues	BL-2
025-2004	Kopin, Alan S	MCRI
	Recombinant Adeno-associated virus (rAAV) BL-2	
(***)	Items so marked indicates Select Agent work.	
(***)	Items so marked indicates at length discussion by Chair and committee (see notations above).	

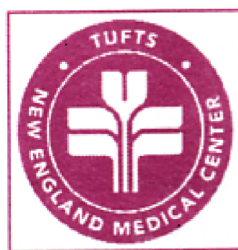
VI. Other Business

- There was no other business to discuss.
- Meeting was adjourned at 1:30 PM.

Approval of Minutes:

Cheleste Thorpe, MD., Chair – Tufts-NEMC Institutional Biosafety Committee

Date



**TUFTS/NEMC
INSTITUTIONAL BIOSAFETY COMMITTEE
Meeting Minutes
Sackler 220
March 22, 2005**

Members Present:

Dr. Cheleste Thorpe, Committee Chair, Jeanne Fahey, Ph.D., Yvonne Glendon, MS, RBP Committee Administrator, Karen Rose, R.N., Eli C. Siegel, Ph.D., Sam R. Telford, III, Sc. D, Rosemarie Van Camp, Community Representative

Members Absent: Joseph Alroy, DVM, David Lazinski, Ph.D., Daniel Liberman, Ph.D., Non-Tufts Member; Dr. Matthew Waldor

Guests: Peggy Newell, J.D., Vice Provost, William New, VP., Research Administration-Tufts-NEMC, Kirk Martin, CBSP, Assistant Biosafety Officer-Grafton, Dr. Walter Lech, Molecular Biology & Microbiology, Nicholas Magliano, Director of EH&S, Katherine Cederberg, representative for the Town of Grafton, MA

Call to order:

Dr. Thorpe called the meeting to order at 12:20 PM.

I. Introduction of New Members

- a. Ms. Glendon reported that there were no new members at that point. Round table introductions were made for the benefit of the two visitors, Ms. Katherine Cederberg, Town of Grafton representative and Dr. Walter Lech, Post Doctoral Associate from Microbiology Dept. Ms. Glendon stated that the IBC would be getting a new appointment who would be representing the Town of Grafton, and that Ms. Cederberg was kind enough to stand in as temporary representative until the final appointment is made.

II. Old Business

a. Review of Minutes

- i. Mr. Kirk Martin noted that his name should appear under 'Guests', not 'members'. Mr Martin also questioned that the information/findings of the Botulinum toxin subcommittee were not included in the minutes. Ms. Glendon clarified that only conversations that took place during the IBC meeting should be found in the minutes for that meeting.
- ii. Noting the items above, the committee voted unanimously to approve the minutes of the August 5th, 2004 meeting.

- b. Update of Tufts Status – Select Agent Program (discussion began upon the arrival of Ms. Peggy Newell, University Vice Provost, and completion of discussion of items III c,d,e, and f below)
- i. Ms. Glendon happily reported that registration was almost complete. Because of architectural issues with the BL-3 suite, the CDC had advised to split the registration, and get the BL-2/toxin suite registration completed. Ms. Glendon reported that full approval has been approved for the BL-2/Toxin Select Agent Facility. She added that we are in the final stages of balancing and certification for the BL-3 suite, with only 4 items noted by the CDC in their inspection that needed to be completed. Completion of work should be no later than April 30th, with submission to CDC for an amended registration by May 1st.
- III. New Business – The committee opted to forgo some new business discussions until Peggy Newell, Vice Provost was present. (Please refer below to item “D” Discussion of Dr. S.T.’s rDNA # 2005-017)
- a. The Sunshine Project & Biosafety Bytes – Ms. Peggy Newell commented on the project, which involved an assessment of institutional biosafety committees across the country. The criteria upon which programs were judged were set by the authors themselves, not by an objective outside standard. She noted that in accordance with NIH requirements, IBC meeting minutes, upon request, should be available to the public. Many institutions did not know that and declined to release them. Tufts provided its minutes. Ms. Glendon stated that the manner in which the request was initially delivered, by single page FAX, was confusing and escaped her attention. Ms. Glendon responded within 24 hours of a second notice, a telephone call. Dr. Thorpe questioned if they should be made available on line. Ms. Newell stated that this is not required and that it is not our intent to change our current practice at this time. Many reporting institutions provided heavily redacted minutes. Ms. Glendon continued that according to NIH guidelines, there are a number of mechanisms by which the minutes of meetings may be made available to the public, from printed material, to allowing public review on site, some post on website, and others. Dr. Jefferson added that even the CDC did not respond to the request of the Sunshine Project. Continuing, Dr. Jefferson felt that it was critical to remove the names or locating information in order to protect scientific professionals. Ms. Newell stated that she would expect a policy going forward that if we get a request for the minutes, they be provided, with identifying information redacted. Ms. Glendon agreed that this was a good idea and resolved to do that, while still providing general information such as Medford, Boston or Grafton, so that those persons who request the minutes have some idea what is being done. Ms. Glendon asked the committee if instead of the current format if they would like to receive all BL-1 and BL-2 protocols that are currently administratively approved by her in a change of the review process. All members agreed that the current system was working very well, enabling scientists to initiate studies in between meeting cycles.
- b. Discussion of Grafton Community By-Laws – Peggy Newell explained that the bylaws of the town of Grafton require that the IBC have a representative from that town. It was believed, previously, that this requirement was covered by a member from the community that lived less than a mile from the campus. Ms. Glendon was unaware of the Grafton By-Laws stipulating that the member must be appointed or offered for appointment by the Town, and appointed by Ms. Newell. Ms. Newell stated that we are now in a position of understanding, and that we are waiting for the individual’s name and resume to be provided to the committee. Ms. Cederberg stated that it would be the LEPC (Local Emergency Planning Committee from Grafton) that would make the appointment at the Town level.
- c. Jaharis 401-BL-3 Suite
- i. Interlock failure – Dr. X thanked the committee for allowing him to detail the events that occurred in the BL-3 suite on the XXX. An individual had become locked in

the exit vestibule. Persons in the laboratory notified Tufts Police, who in turn notified Ms. Glendon. Upon arrival at the location, Ms. Glendon asked for Facilities to come to the lab, as well as a Tufts Police officer. It was determined that the card reader was not operating properly, in addition to several other locks, mag lock, and 'interlocks' not functioning as designed. The individual was released from the exit vestibule when the police used the key override, which released the lock on the exit door.

1. In follow up investigations, it was found that the door from the lab into the exit door had not completely closed, and as a result, the interlock would not release to allow the next door to open.
 2. It is important to note two things, one, there was not yet any active infectious work going on, and two, at no time was there ever any question that there was a loss of negativity and containment for the suite.
 3. Ms. Glendon stated a question about practices, referring to Dr. H's BL-3 lab on the X floor. She continued that they discovered early on that they could only use the UV function on one BSC (biological safety cabinet) at a time, since the balancing of air/negativity depends on volumes of air passing through the BSCs into the duct work. And if both sashes were down simultaneously, the negativity in the suite would drop (become more positive) and the alarms would go off. Dr. X reported that this problem occurred at a time when in fact there was only one BSC in the closed position.
- ii. Temporary reduction of Dr. C's Biosafety Level from BL-3 to BL-2+ - Ms. Glendon introduced this request saying that since this was work over BL-2, the entire committee needed to make the decision on lowering the safety level. She continued by explaining that clinical diagnostic specimens, even with HIV, may be worked on at BL-2. But, when one begins to grow up quantities of the virus, NIH stipulates that work be done at BL-3. Ms. Glendon stated that she had been informed that the intended work had no infectious component, it was not the entire genome of the virus and that it was not infectious. Dr. Thorpe and Dr. X discussed the history of this particular strain of the HIV virus—it appears that the laboratory is growing an HIV strain that has a mutation in nef, and thus has decreased virulence, but is still infectious. Ms. Glendon inserted that this work needed to be registered with the committee, and it was not yet submitted. The full committee would then have to meet to discuss this registration. Dr. X was assured that when the appropriate registration is sent in, an urgent meeting of the IBC would be called to determine if approval could be made, so that their work would be facilitated if possible. Ms. Glendon explained that registrations are submitted electronically, reviewed and sent back for investigator review, printing and signature. By archiving electronically, the renewal process is facilitated both for the safety office as well as the PI.
1. The issue of the malfunction of the autoclave, not alarming and allowing both doors to be opened simultaneously was briefly discussed. The Department manager will contact the company to inquire about this failed mechanism.
 2. Ms. Cederberg offered that this is an important item that needs to be addressed. She was assured by Ms. Newell and Ms. Glendon that all of the issues would be addressed and corrected.
 3. Dr. X discussed the bioreactor for the work he intends to do, which will be covered by the registration that Dr. C's Lab will submit. Mr. Martin inquired as to the potential for worker exposure. Dr. X explained the design of the system, and that it was completely closed. The committee

- recommended that Ms. Glendon inspect the equipment to verify the safety of the design and the operation.
4. Ms. Newell assured the committee that she would contact Mr. JR, Director of Operations about the discussed issues. Mr. Martin suggested that the department contact Ranger Engineering, as they are known by him to be an excellent choice for general autoclave service, since the unit is no longer under warranty
 5. Ms. Glendon briefly explained the protocol submission, renewal and expiration process for Ms. Cederberg so that she might have a better understanding of the materials that had previously been submitted to Ms. Lois Luniewicz. Ms. Glendon offered to provide the blank forms for review so that they might be more easily understood.
- d. Discussion – Dr. T’s rDNA # 2005-017 – All members had received the protocol via e-mail attachment. Dr. Thorpe questioned Dr. T regarding the SSTR markers and whether or not he thought he was amplifying anything containing an open reading frame. Dr. T. responded that the amplicon contained a truncated construct, with only a piece of an open reading frame. Dr. Thorpe stated that with that clarification, she had no other problems with the protocol, and asked if anyone else had questions. Ms. Glendon requested that Dr. T. submit a one page submission detailing this work. This paper, along with the rDNA registration must be submitted to the CDC/SAP for review and approval by a specially convened committee. The committee voted unanimously to approve Dr. T’s rDNA # 2005-017 “Variability in short sequence tandem repeat markers of *Francisella tularensis*” - BL-3
- e. Discussion – Ms. Glendon stated that Mr. Martin had asked for full committee review of Dr. D. W’s infectious agent registration # 033-2004 – *Mycobacterium tuberculosis*, ATCC # 25177, administratively approved at BL-2. Mr. Martin asked if it was a renewal or a new registration. Ms. Glendon stated that it (and two others for Dr. W.) were new. Ms. Glendon continued that the PI had originally stated that the work would be done in a laminar flow hood, which is unacceptable for worker protection at BL-2. Ms. Glendon provided extensive information and support for Dr. W. to move the decision process towards purchase of a biological safety cabinet for the work. Mr. Martin reported that this is a particular strain of TB that has been widely used, that it is a avirulent strain, most studies for avirulence in mice and guinea pigs. A 1922 strain virulence study showed wide variation in strain virulence, depending on culture conditions. ATCC does recommend it as BL-2, and has been used at that level historically. Mr. Martin pointed out that currently this is topic for discussion among Biosafety professionals at Harvard University, as to what is the proper safety conditions, and also effective antibiotics. Mr. Martin continued that it is used as a comparison against clinical isolates, and in CAP proficiency testing. Dr. Jefferson offered that there should be some TB screening done on workers. Dr. Thorpe discussed the possibility for false positive TB screening because many of the workers in the scientific community may have received BCG vaccinations. In addition, Dr. Thorpe made the recommendation that these folks receive the PPD TB screening prior to working with this ‘avirulent’ strain of TB. Peggy Newell had arrived during this conversation and offered that the Hooper Health infirmary would be a likely place for the screening to be conducted. Ms. Glendon stated that she will send a letter to Dr. W. from the committee advising the following: 1) we require that workers are screened with pre-employment PPD testing, and then every 6 months thereafter; 2) we require that the strain be tested to confirm it is indeed the expected strain, and not a mixture of strains that may have different virulence potential; and 3) we require confirmation that this strain is PAN sensitive to the usual drugs to treat tuberculosis, and thus can be controlled if accidental exposure occurs.

The committee unanimously approved the committee's action and the protocol with those stipulations.

- f. Discussion – Mr. Martin also wanted to discuss Dr. R. L.'s infectious agent registration # 001-2005 – Bartha's strain of pseudorabies virus – BL-2. Mr. Martin stated that pseudorabies is an animal reportable disease that has been eradicated from the environment. The Massachusetts Department of Agriculture Resources regulates activities such as this. Dr. L. would need to contact Dr. David Sherman at 617-626-1700 to apply for a "certificate of no action". This would be basically a review of the procedures, the lab equipment. Ms. Newell voiced concerns about the fact that the protocol was currently active (a renewal). Mr. Martin stated that it was new information received by Harvard as well by a veterinarian who happen to be on the IBC there. Ms. Glendon noted that since the Biosafety level was set at BL-2, all waste from Dr. L.'s laboratory would be disinfected/autoclaved prior to disposal, thus providing a level of protection to the environment. Ms. Glendon will send a letter from the IBC to Dr. L. advising him of this state requirement and his need to apply

IV. New Protocols

- a. rDNA Protocols – except where noted by discussion highlights and approvals, all protocols were formerly approved by unanimous vote of the committee members.

2004-031	Expression of Recombinant <i>Listeria monocytogenes</i> Antigens – BL-2
2004-032	Helminth parasite interactions with mammalian hosts – BL-2
2004-033	ABC-transporter binding proteins and trafficking – BL-2
2004-034	Integrin-Dependent Signals Modulate T cell Activation Thresholds – BL-2
2004-035	LMP1 and LMP2 induction of chemokines and adhesion molecules in epithelial cells - BL-2
2004-036	Borrelia-Integrin Interactions – BL-2
2004-037	Pedigree tracking, walk-back selection and linkage mapping of <i>Penaeus vannamei</i> shrimp – BL-1
2004-038	Oral and Intranasal Vaccines against Botulism – BL-1
2004-039	Mechanism of TGFbeta Signal Transduction – BL-1
2005-001	Transcriptional Regulation of Cardiac Development & Heart Failure BL-1 and 2 Approval Date: January 18, 2005 Expiration Date: January 18, 2008
2005-002	Virulence Factors Affecting the systemic dissemination of Y. Pseudotuberculosis – BL-2 Approval Date: January 18, 2005 Expiration/Renewal Date: January 18, 2008
2005-003	Regulators of Cartilage development – BL-2 Approval Date: January 18, 2005 Expiration Date: January 18, 2008
2005-004	TRH and Energy Homeostasis – BL-1 Approval Date: January 31, 2005 Expiration Date: January 31, 2008
2005-005	Production of FAP gene knockout mice for hematopoietic investigation – BL-1 Approval Date: January 31, 2005 Expiration/Renewal Date: January 31, 2008
2005-006	Muropeptide recycling pathway and beta-lactamase induction – BL-2 Expiration/Renewal Date: February 1, 2008
2005-007	Lbc Oncogene Function – BL-2 Expiration/Renewal Date: February 1, 2008
2005-008	Optical Fiber Two Hybrid Yeast – BL-1 Expiration/Renewal Date: February 1, 2008
2005-009	Cloning, characterization and expression of <i>C. parvum</i> genes – BL-2 Expiration/Renewal Date: February 1, 2008
2005-010	Cloning, characterization and expression of <i>Cryptosporidium</i> genes – BL-2 LARGE SCALE work done at GRASP center – Dr. Anne Kane

- 2005-011 **Expiration/Renewal Date: February 1, 2008**
LARGE SCALE Purification of Tetracycline Efflux Antiporter TetA protein in E. coli for use in Crystallization for X-ray Diffraction and Structure and Function studies – BL-2 Large Scale
Expiration/Renewal Date: February 4, 2008
- 2005-012 Inducible Surface Hydrophobicity of Microbial Consortia for Biofilm Remediation – BL-1
Expiration/Renewal Date: February 4, 2008
- 2005-013 Metabolic Engineering for Natural Product Biosynthesis – BL-1
Expiration/Renewal Date: February 8, 2008
- 2005-014 Bio 50, Experiments in Molecular Biology Lab Course – BL-1 Exempt
- 2005-015 Smooth Muscle Cell Growth Control by CCN5 – BL-2
Expiration Date: February 23, 2008
- 2005-016 Structure and Function of Ion Channels formed by the Protective Antigen Component of Anthrax Toxin – BL-2
Expiration Date: March 8, 2008
- 2005-017 **(***)** Variability in short sequence tandem repeat markers of Francisella tularensis – BL-3
Reviewed by full committee see discussion above – Select Agent Use

b. Infectious Agent Registrations

- 026-2004 Yersinia pseudotuberculosis – BL-2
- 027-2004 Recombinant adeno-associated virus – BL-2
- 028-2004 Replication Deficient Adenovirus – BL-2
- 029-2004 Recombinant adeno-associated virus – BL-2
- 030-2004 Use of human source materials – BL-2
- 031-2004 Borrelia burgdorferi – BL-2
- 032-2004 Cytomegalovirus, ATCC#VR-538 – BL-2
- 033-2004 Mycobacterium tuberculosis, ATCC#25177 – BL-2
Committee requires that Dr. X have workers screened for TB, and the strain must be confirmed to be PAN sensitive so that it can be controlled. Letter to go to Dr. X from the committee. Committee upheld approval with conditions stated above.
- 034-2004 Human lung fibroblast cells MRC-5, ATCC#CCL-171 – BL-2
- 035-2004 Pseudomonas aeruginosa – BL-2
- 036-2004 Human blood – BL-2
- 037-2004 Human cell lines, retrovirus packaging DNA – BL-2
- 038-2004 Lactobacillus Casei – BL-1
- 039-2004 Potential Herpes B in SIV infected animals – BL-2
- 040-2004 EBV – BL-2
- 041-2004 Pseudomonas aeruginosa – BL-2
- 001-2005 Bartha's strain of pseudorabies virus – BL-2
Expiration Date: January 31, 2008
 See discussion in meeting minutes above, Dr. X will be advised to contact Dr. David Sherman at the Mass. Dept. of Agricultural Resources – Approval upheld with condition that environmental compliance certificate is completed by Dr. X
- 002-2005 Human breast tumor cell lines – BL-2
Expiration Date: February 1, 2008
- 003-2005 Cryptosporidium hominis – BL-2
Expiration Date: February 1, 2008
- 004-2005 Toxoplasma gondii – BL-2
Expiration Date: February 1, 2008
- 005-2005 Adenovirus and culture of HEK293 cells – BL-2

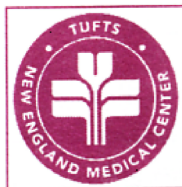
Expiration Date: February 1, 2008

- VI. Other Business –**
- a. There was no other business to discuss.**
 - b. Meeting was adjourned at 1:50 PM.**

Approval of Minutes:

Cheleste Thorpe, MD., Chair – Tufts-NEMC Institutional Biosafety Committee

Date



TUFTS/NEMC
INSTITUTIONAL BIOSAFETY COMMITTEE
Meeting Minutes
Sackler 208
October 3, 2005

Members Present:

Dr. Cheleste Thorpe, Committee Chair, Joseph Alroy, DVM, Andrew Cederberg, Ph.D., Jeanne Fahey, Ph.D., Douglas Jefferson, Ph.D., Yvonne Glendon, MS, RBP
Committee Administrator, Rosemarie Van Camp, Community
Representative, Dr. Matthew Waldor

Members Absent: Karen Rose, R.N., Eli C. Siegel, Ph.D., Sam R. Telford, III, Sc. D, Daniel Liberman, Ph.D.

Guests: Peggy Newell, J.D., Vice Provost, Diane Gilbert, VP., Research
Administration-Tufts-NEMC, Kirk Martin, CBSP, Assistant Biosafety
Officer-Grafton, Nicholas Magliano, Director of EH&S

Call to order:

Dr. Thorpe called the meeting to order at 12:30 PM.

I. Introduction of New Members

- a. Ms. Glendon introduced the newest member to the committee, Dr. Andrew Cederberg, who is a representative from the town of Grafton. Round table introductions were made for the benefit of Dr. Cederberg.

II. Old Business

a. Discussion of proceedings of previous meeting:

- i. Dr. Thorpe discussed the conversations of the prior meeting regarding the BL-3 suite in Boston, and how she felt that we may have inadvertently left the visitor from the Town of Grafton with the impression that we 'didn't care' about the issues in the BL-3 suite. Dr. Thorpe clarified that it wasn't that we did not care, it was that there was no one present at the meeting who would be able to make the decisions involving facility issues. Ms. Newell pointed out that the discussion at the meeting assumed that everyone understood that the person could have gotten out of the suite, but chose not to break the glass. Dr. Thorpe continued that things that are certainly obvious to people who work in these kinds of facilities are not readily obvious to outside persons. The true intent of the reason for Dr. Waltr Lech attending the meeting was to inquire about the level of work that he could do in the BL-3 suite, until things got fixed, not to discuss the outstanding facility issues. Ms. Newell stressed that at no time were we 'endangering a worker in the space. (Dr. Andrew Cederberg arrived at the meeting approximately 15 minutes after convening.)(Was introduced as noted above)

pnewell 11/16/05 1:13 PM

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pnewell 11/16/05 1:14 PM

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- b. Review of Minutes
 - i. The minutes of the previous meeting were reviewed and approved unanimously by the committee with no changes, corrections or amendments.
- c. Update of Tufts Status – Select Agent Program
 - i. Ms. Glendon reported that registration was fully approved, for both the BL-2/Toxin suite as well as the BL-3 suite. (Two and a half years worth of work!)
 - ii. Dr. Thorpe discussed Select Agent registration for Tufts-NEMC. Dr. Thorpe explained that the amounts of agent that is being worked on is exempted. However, the process of putting the genes for the toxin into the species that she is working with would thus necessitate that NEMC register with the SAP. NEMC asked the CDC/SAP if they could get a letter of exemption. There has been considerable communication to the program and to date, no response. Ms. Glendon explained that it can take a very long time to go through the process. Dr. Thorpe explained that she did not want the NIH to come back in a year and say “you received your letter of acceptance and you never registered with SAP...” and then recall the grant. Dr. Thorpe continued that Mr. Burgess had requested an action, and not heard back. Ms. Newell suggested keeping track of all that paperwork. Ms. Glendon suggested that the registration be filed with all necessary paperwork. This puts the cycle in motion, an accession number is given and the paperwork is then internally tracked at the CDC/SAP office, thus putting the process formally in motion.

New Business – Kirk Martin, Assistant Biosafety Officer on the Grafton Campus reported on a series of drills for Grafton Fire and Pathways ambulance, starting with a table top drill on Saturday, the 17th and then an actual drill with Grafton Fire and Pathways ambulance on Saturday, the 24th. There were approximately 30-35 people at the tabletop, Tufts Police, LEPC, Grafton police & fire, EH&S, Scientists running the facility, Tufts Facilities director, taking about 3 hours, with 3 different scenarios for each suite location. Kirk discussed the lessons learned, one being that perhaps the fire fighter’s gear might get contaminated or destroyed by the bleach used to decontaminate it. We are hoping to find alternatives to bleach, such as quaternary ammonia. The hands on exercise was to give the fire department a chance to have an opportunity to walk through the facility, get used to the lay out, etc. Grafton fire would only respond to an actual fire. If a fire is called, the ambulance company is automatically called as well. For the BL-3 exercise, we had an unconscious victim in the BL-3, second scenario was a researcher bitten by an infected mouse, researcher able to do their own decontamination and then brought to hospital by ambulance. The last scenario autoclave controls caught on fire, activating the sprinkler system. Two researchers evacuated out of the suite through the emergency exit, doing decontamination on site for people, helping fire fighters frame an appropriate response to this scenario. Purpose of holding drills, we want to have regular, annual drills for the fire fighters to get them more comfortable, and practice donning PPE and medical decontamination to be able to extract victims as quickly as possible. We also wanted to practice for our facilities people to remotely control the HVAC systems.

For Building 21, manual key pads inside building. Fire fighters felt this might be a hazardous slow down. Director of facilities is working on changing to key card access which gives us ability to control open/lock remotely, or the Tufts Police officer could swipe to open the doors to get fire fighters in.

Pathways already have their own standard SOP’s. It took approximately 3 ½ hours for the actual drill. The Grafton Fire Chief as well as the Deputy Fire Chief were in attendance. One interesting exercise was the victim extraction from the BL-3 suite, using a backboard. This is interesting because the shower is a 90 ° corner, making it necessary to actually stand the back board up to get the victim through to the ante room. Dr. Cederberg inquired as to whether or not there was a ‘change of attitude’ after the drills. Kirk explained that this was

not the first time we had met with the group, and he feels that each time the communication between Tufts and the responders gets better and achieves a greater level of comfort for the responders. Dr. Cederberg continued to explain about the information he had heard from conversations with Grafton community folks, that the funding had come from the bioterrorism/Patriot Act and the Homeland Security, point which was clarified by both Ms. Glendon and Ms. Newell that funds for this research did in fact come from NIAID, because they are concerned about bioterrorist. Mr. Martin provided clarification regarding information he had previously given to the LEPC in answer to questions of survival rates in the environment.

III. New Protocols - except where noted by discussion highlights and approvals, all protocols were formerly approved by unanimous vote of the committee members.

a. rDNA Protocols

ygglend01 11/16/05 1:34 PM

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ygglend01 3/20/06 1:52 PM

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2005-018

Shang, Fu

Nutrition & Vision Research Lab

Role of Ubiquity-proteasome pathway in the eye – BL-2

Expiration/Renewal Date: April 11, 2008

2005-019

Talavera, Joyce

Heme/Onc.

A Randomized, Phase II Study of TNFERADE Biologic With 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer. – BL-2

Expiration/Renewal Date: April 20, 2008 –full IBC members were provided with electronic copies of the protocol for review and voting.

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2005-020

Sonenshein, Abraham

Molec. Bio & Micro

Bacillus subtilis vaccine strains – BL-2

Expiration/Renewal Date: April 20, 2008

ygglend01 3/20/06 1:52 PM

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2005-021

Herman, Ira

Physiology

Regulating retinal microvascular morphogenesis – BL-1

Expiration/Renewal Date: April 27, 2008

ygglend01 3/20/06 1:52 PM

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2005-022

Kumamoto, Carol

Molecular Biology and Microbiology

Genetic analysis of morphogenesis and virulence in Candida albicans- BL-1

Expiration/Renewal Date: April 29, 2008

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2005-023

Finlay, Geraldine

Medicine, Div. Pulmonary and Critical care

The role of tuberin in smooth muscle cell growth – BL-1

Expiration/Renewal Date: April 29, 2008

ygglend01 3/20/06 1:52 PM

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ygglend01 3/20/06 1:52 PM

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2005-024

Thorpe, Cheleste

Geographic Med-Div of Inf. Disease

Shiga Toxin – BL-2

Expiration/Renewal Date: April 29, 2008

ygglend01 3/20/06 1:52 PM

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ygglend01 3/20/06 1:53 PM

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2005-025

Forgac, Michael

Physiology

Structure, Mechanism and Regulation of the V-ATPases – BL-1

Expiration/Renewal Date: May 2, 2008

ygglend01 3/20/06 1:53 PM

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ygglend01 3/20/06 1:53 PM

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2005-026

Moore, Claire

Mol. Bio & Micro

Biochemical and genetic analysis of mRNA 3' – BL-1

Expiration/Renewal Date: May 3, 2008

ygglend01 3/20/06 1:53 PM

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ygglend01 3/20/06 1:53 PM

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2005-027

Rosenberg, Naomi

Pathology

ygglend01 3/20/06 1:53 PM

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Abelson Leukemia Virus Transformation – BL-1

Expiration Date: June 2, 2008

2005-028	Dawson, Dean Microbiology Identification of compounds that potentiate the spindle checkpoint – BL-1 Expiration Date: June 2, 2008	yglend01 3/20/06 1:53 PM Deleted: 60393 yglend01 3/20/06 1:53 PM Deleted: – M&V 404
2005-029	Stollar, David Biochemistry Recombinant Antibody Variable Regions – BL-1 Expiration Date: June 6, 2008	yglend01 3/20/06 1:54 PM Deleted: 64948 yglend01 3/20/06 1:54 PM Deleted: – M&V 602
2005-030	Chen, Jake Dental Building Cell Differentiation in Periodontal Regeneration – BL-2 Expiration Date: June 7, 2008	yglend01 3/20/06 1:54 PM Deleted: 62729 yglend01 3/20/06 1:54 PM Deleted: Lab 633
2005-031	Waldor, Matt Microbiology Molecular genetics of Vibrio cholerae virulence – BL-2 Expiration Date: June 10, 2008	yglend01 3/20/06 1:54 PM Deleted: 62730 yglend01 3/20/06 1:54 PM Deleted: Jaharis 425
2005-32	Leavy, Stuart Molecular Biology & Microbiology Use of rDNA techniques in the studies of genes for antibiotic resistance and persistence in bacteria and mammalian genes for drug resistance ~ BL-1* Expiration Date: June 14, 2008	yglend01 3/20/06 1:54 PM Deleted: MV 8 yglend01 3/20/06 1:54 PM Deleted: 66764
2005-033	Coffin, John Microbiology Integration and expression of retrovirus DNA – BL-2 Expiration Date: June 21, 2008	yglend01 3/20/06 1:54 PM Deleted: Jaharis 401 . . . 66528
2005-034	Dice, James Physiology Protein Degradation in Aging Human Fibroblasts Expiration Date: July 18, 2008	yglend01 3/20/06 1:54 PM Deleted: Arnold 809 . . . 66707
2005-035	Sonenshein, Abraham Micro & Mol Bio Regulation of Bacillus subtilis genes	yglend01 3/20/06 1:54 PM Deleted: Arnold 508 . . . 66761
2005-036	Linseny, Thomas F. Anatomy & Cell Biology Corneal Stroma Synthesis and assembly of Collagens – BL-1 Expiration Date: August 17, 2008	yglend01 3/20/06 1:54 PM Deleted: Jaharis 339A-D . . . 66695
2005-037	Gordon Huggins, MD Tupper DLAM facility, Transgenic Core, MCRI/Tufts New England Medical Center Alcohol and muscle stem cells BL-2 Expiration Date: August 17, 2008	yglend01 3/20/06 1:55 PM Deleted: 13 yglend01 3/20/06 1:55 PM Deleted: 62807 .
2005-038	Gounari, Fotini MORI Development and transformation in the DN to DP thymocyte Transition – BL-2 Expiration Date: September 28, 2008	yglend01 3/20/06 1:55 PM Deleted: Tupper 13 yglend01 3/20/06 1:55 PM Deleted: 75 Kneeland . . . 66038

B. Infectious Agent Registrations

007-2005	Thorpe, Cheleste Tupper Shiga toxin-producing E. coli – BL-2 Expiration Date: February 16, 2008	GeoMed/ID	▼	ygglend01 3/20/06 1:55 PM Deleted: 60245
008-2005	Levy, Stuart Yersinia pestis (attenuated) – BL-2 Expiration Date: February 23, 2008	Mol. Bio & Micro	▼	ygglend01 3/20/06 1:55 PM Deleted: 511
009-2005	Levy, Stuart Mycobacterium smegmatis – BL-2 Expiration Date: February 23, 2008	Mol. Bio & Micro	▼	ygglend01 3/20/06 1:55 PM Deleted: M&V 803
010-2005	Castellot, John Adenovirus – BL-2 Expiration Date: February 23, 2008	Anatomy & Cell Biology	▼	ygglend01 3/20/06 1:56 PM Deleted: 66764
011-2005	Adams, Sharleen Biosafety Level 2: The human tumor cell line commonly known as HT-29, obtained from the A.T.C.C., which is not known to harbor an agent known to cause disease in healthy adult humans. Biosafety Level 1: The mouse tumor cell line commonly known as 4T1, obtained from the A.T.C.C., which is not known to harbor an agent known to cause disease in mice or in healthy adult humans. Expiration Date: March 11, 2008	Point Therapeutics, Inc.	▼	ygglend01 3/20/06 1:56 PM Deleted: 60303
012-2005	Behera, Aruna K. Human metapneumovirus – BL-2 Expiration Date: March 11, 2008	Geographic Med	▼	ygglend01 3/20/06 1:56 PM Deleted: 617-933-2151
013-2005	Kopin, Alan Replication –defective lentivirus for expression of wild-type and constitutive active cholecystokinin type 1, melanocortin-4 sybtype, dopamine, and selected other GPCRs. Additional lentivirus constructs will encode RGS proteins, luciferase reporter genes, G proteins, etc. Expiration Date: March 31, 2008	MCRI	▼	ygglend01 3/20/06 1:56 PM Deleted: 67613
014-2005	Talavera, Joyce TNFerade™ biologic (Ad _{GV} EGR.TNF.11D) is an E1, E4, partial E3- replication deficient adenovirus Review Date: April 20, 2005 Must be reviewed by full IBC for full approval	Hematology/Oncology	▼	ygglend01 3/20/06 1:56 PM Deleted: Tupper 615
015-2005	Weinstock, Joel Tupper Schistosoma mansoni – BL-2 & Heligmosomoides polygyrus – BL-1 Expiration Date: April 20, 2008	Internal Medicine TBD	▼	ygglend01 3/20/06 1:57 PM Deleted: 64834
016-2005	Vannier, Edouard Tupper Babesia microti – BL2 Expiration Date: April 25, 2008	Medicine	▼	ygglend01 3/20/06 1:57 PM Deleted: Tupper 7
017-2005	Selsing, Erik Jaharis B. anthracis (stearns strain) – BL-2 Expiration Date: April 26, 2008	Pathology	▼	ygglend01 3/20/06 1:57 PM Deleted: 65818
018-2005	Shoemaker, Charles H. polygyrus – BL-1 Expiration Date: April 28, 2008	Div. of Inf. Disease	▼	ygglend01 3/20/06 1:57 PM Deleted: 636-8526

019-2005	Finlay, Geraldine Medicine, Div. Pulmonary and Critical care Adenovirus and Retro virus replication deficient containin recombinant genes – BL-2 Expiration Date: April 29, 2008	yglend01 3/20/06 1:57 PM Deleted: 67751 yglend01 3/20/06 1:57 PM Deleted: Tupper 3, #NEMC 257
020-2005	Klingman, Hans Human source material – BL-2 Expiration Date: April 29, 2008	yglend01 3/20/06 1:57 PM Deleted: 62270 yglend01 3/20/06 1:57 PM Deleted: 75 Kneeland St. 10 th floor, rm 10006
021-2005	Subsequent renewal sent and registered under 025-2005 for Dr. Barnett	yglend01 3/20/06 1:58 PM Deleted: Barnett, Junaidah, Friedman School of Nutrition Science 136 Harrison Jaharis 60813 Use of Human tissues/blood – BL-2 Expiration/Renewal Date: 11/11
022-2005	Georgakoudi, Irene Biomedical Engineering Human breast cells – BL-2 Expiration Date: May 3, 2008	yglend01 11/16/05 1:36 PM Deleted: yglend01 3/20/06 1:58 PM Deleted: 4 Colby Street 74353 yglend01 3/20/06 1:58 PM Deleted: 62991 Arnold 801 yglend01 3/20/06 1:58 PM Deleted: 617-933-2151 75 Kneeland, 10 th Floor
023-2005	Herman, Ira Physiology EHEC and EPEC – BL-2 Expiration Date: May 4, 2008	
024-2005	Adams, Sharlene Point Therapeutics Biosafety Level 2: The human tumor cell line commonly known as LS180, obtained from the A.T.C.C. The human tumor cell line commonly known as Namalwa, which is also obtained from the A.T.C.C. and which an EBV-transformed B cell line that carries an integrated form of the EBV genome. Biosafety level 1: The mouse tumor cell lines commonly known as Lewis lung carcinoma, B16-F0, B16-F10, WEHI 164, EL4, E.G7-OVA, P815, and A20, obtained from the A.T.C.C., are not known to harbor an agent known to cause disease in mice or in healthy adult humans. Expiration Date: June 1, 2008	
025-2005	Barnett, Junaidah Nutritional Epidemiology Use of Human Blood – BL-2 Expiration Date: June 1, 2008	yglend01 3/20/06 1:58 PM Deleted: 60813 Jaharis 2
026-2005	Rowell, Steven L. Biomedical Sciences Attenuated vaccinia virus vaccine – BL-1 Approval Date: June 2, 2005 Expiration Date: June 2, 2008	yglend01 3/20/06 1:58 PM Deleted: 88730 FHSA – Grafton
027-2005	Leav, Brett A. Tupper 515 Cryptosporidium parvum species – BL-2 Approval Date: June 2, 2005 Expiration Date: June 2, 2008	yglend01 3/20/06 1:58 PM Deleted: 68437 Geographic Medicine
028-2005	Jay, Daniel Physiology Human breast cancer cell lines SUM1315MO2 and MDA-MB-231, biosafety level 2 Expiration Date: June 7, 2008	yglend01 3/20/06 1:58 PM Deleted: M&V 709 66764
029-2005	Waldor, Matthew Microbiology Vibrio cholerae – BL-2 Expiration Date: June 10, 2008	yglend01 3/20/06 1:59 PM Deleted: Jaharis 425 62730
030-2005	Wortis, Henry Pathology Babesia microti – BL-2	yglend01 3/20/06 1:59 PM Deleted: Jaharis 801 66718

Expiration Date: June 21, 2008

031-2005	Herrman, John Biomedical Sciences Hepatitis A – BL-2, also attenuated strain at BL-1 Expiration Date: July 11, 2008	yglend01 3/20/06 1:59 PM Deleted: Bldg. 21 . . . 84372
031-2005	Coburn, Jenifer NEMC GeoMed/ID L. interrogans, borgpetersenii, kirschneri – BL-2 Expiration Date: July 18, 2008	yglend01 3/20/06 1:59 PM Deleted: Tupper 6 . . . 65952
031-2005	Kaplan, David Use of Human Source Materials – BL-2 Expiration Date: July 19, 2008	yglend01 3/20/06 1:59 PM Deleted: Biomedical Engineering . 73251
032-2005	Meydani, Simin Nutritional Immunology <i>Yersinia enterocolitica</i> and <i>Salmonella Typhimurium</i> Expiration Date: August 8, 2008	yglend01 3/20/06 1:59 PM Deleted: 4 Colby Street . Labs 285, 277 283 . yglend01 3/20/06 1:59 PM Deleted: 617-556-3129 HNRCA .
033-2005	Maribel Rios Neuroscience Adenovirus associated virus (AAV)-Cre recombinase and AAV-EGFP viruses ` BL-2 Expiration Date: August 17, 2008	yglend01 3/20/06 1:59 PM Deleted: 62748 Stearns 324
034-2005	Kumamoto, Carol Molecular Biology and Microbiology <i>Candida albicans</i> – BL-1 Expiration Date: August 22, 2008	yglend01 3/20/06 1:59 PM Deleted: 60404 . Stearns 502/503
035-2005	Tzipori, Saul Div. of Infectious Disease <i>Bacillus subtilis</i> – BL-1 Expiration Date: August 25, 2008	yglend01 3/20/06 1:59 PM Formatted: Indent: Left: 0", First line: 0" yglend01 3/20/06 2:00 PM Deleted: 84586 Building # 20
	Dr. Thorpe requested the committee to review and discuss several protocol registrations.	yglend01 11/16/05 1:36 PM Deleted: _____

Materials transfer documents were requested to be provided to the committee when investigators state that they receive research materials from colleagues outside the University.

Discussions were held regarding the verification of attenuation of infectious agents, or proof by the receiver (Tufts investigator) that the agents received are, in fact, the attenuated or replication deficient/incompetent. Thoughts were voiced that the burden of proof should be on the sender, but unfortunately, there is no way to enforce that.

The committee discussed and decided that the Infectious Agent registration form needed to be changed to include questions regarding the verification steps taken by the investigator to assure that materials received are truly the attenuated or deficient ones that were ordered.

Dr. Jefferson led a brief discussion on the fact that even supply houses such as ATCC have cell lines that have been contaminated by mycoplasma viruses.

Discussions on several previously administratively approved registrations were held.

Joel Weinstock # 015-2005 – *Schistosoma mansoni* – BL-2 and *Heligmosomoides polygyrus* – BL-1 Group is working with an infectious stage of the parasite, the infected snails that produce the cercaria are kept in a stainless steel pan. To harvest the cercaria, lab personel put on lab coat, face shield, double gloves. Using tongs, worker places the snail in a beaker under bright light for 30 minutes. This causes the snails to shed the cercaria. Cercaria are counted and then mice are infected via injection with the cercaria. Used for > 20 years without any infection. Dr. Thorpe viewed concern that antibody testing for exposure to the *S. mansoni* had not been offered. The

committee determined that people working in Dr. Weinstock's laboratory be offered antibody screening prior to beginning work with the schistosomes, and then annually thereafter. The committee determined that a letter be sent to Dr. Weinstock to recommend that the screening be offered.

Aruna K. Behera, MD # 012-2005 – Human metapneumovirus – BL-2 – is a relatively newly recognized virus, low pathogenic agent; it is a respiratory viral entity and Dr. Thorpe felt that serum banking, as detailed in the registration should not be done. Pre-employment serum samples should never be banked except in most extreme situations because we have no place to bank, no way of keeping samples properly stored. The statement should be taken out of the protocol. BSC used, work done in hood. A letter will be sent to Dr. Behera.

Erik Selsing, Ph.D. # 017-2005 – Use of Bacillus anthracis, stearn strain, exempt from Select Agent rule. Discussions held again regarding need for investigator to provide documentation that the strain received is actually the attenuated, exempt strain that was ordered.

Rosemarie VanCamp inquired as to the current knowledge base and preparations underway nationally for development of a 'bird flu vaccine'. Dr. Waldor discussed the science of the mutations needed to have the virus become the next pandemic, and the potential to use the current bird flu virus to make a vaccine. The possibility exists that sufficient vaccine supply could not be made in time. Other medications, such as Tamiflu would provide some assistance, but again, there is not enough Tamiflu for everyone in the US.

Brief discussions were held regarding the public release of the full genetic code of the 1918 Spanish flu, and all the implications of possible use of the information to terrorists for a bioweapon. The current bird flu H5N1 virus is actually related to the 1918 Spanish flu. Not currently infectious, only from bird to bird or bird to human. Does not currently spread from human to human.

Dr. Cederberg asked a procedural question regarding how protocols are approved. Ms. Glendon explained that all of the protocols for the current meeting had already been previously approved administratively. If protocols needed review by the entire committee, IE., BL-2+ or higher, select agent or ones involving humans, they would have been distributed to members prior to the meeting.

Another discussion was held regarding the inadvertent shipment of the Hong Kong flu virus by the CDC? in the CAP proficiency surveys, and how people had to deal with destroying it and documentation that it had been destroyed. It is not the same as the current bird flu virus.

A brief discussion regarding the handling of Dr. Talavera's protocol by sending out electronically to members (due to people being away in the summer). There was no issues of concern for the manner in which it was handled.

- VI. Other Business –
- a. There was no other business to discuss.
 - b. The meeting was adjourned at 2:00 PM

Approval of Minutes:

Cheleste Thorpe, MD., Chair – Tufts-NEMC Institutional Biosafety Committee Date