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July 25, 2006



Via Registered Mail

Edward H. Hammond
Director, the Sunshine Project
P.O. Box 41987
Austin, Texas 78704

Dear Mr. Hammond:

In response to your national survey of compliance with NIH Guidelines, attached please find the meeting minutes for the period specified for research conducted at The Institute for Genomic Research (TIGR).

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Wellman', with a long horizontal flourish extending to the right.

Katherine M. Wellman
Biosafety Officer
Institutional Biosafety Committee

Institutional Biosafety Committee Meeting Minutes
The Institute for Genomic Research
January 24, 2005
10:00 a.m. Building 5 room 100

1. Meeting members

Leslie Bisignano, Najib El-Sayed (Chair), Elodie Ghedin, Steven Gill, Hanif Khalak, Barbara Methé, David Narum, Clyde Ragland (Biological Safety Officer), Chris Town & Katherine Wellman.

2. Report from the IBC chair on action items from last meeting

- 2.1 The chair introduced new member Katherine Wellman, Director of Environmental Health and Safety
- 2.1 The chair reported on a full inventory of all existing projects at TIGR that was performed as part of the response to an inquiry letter from the OBA/NIH. TIGR IBC was found in compliance with the NIH guidelines for the use of recombinant DNA.
- 2.2 Registration of TIGR's IBC with the OBA for 2005 is completed.
- 2.3 All the members of the TIGR IBC were asked to sign a non-disclosure agreement (NDA) which was prepared by Michael Brown. Confidential information relates to projects that are being carried out in collaboration with various federal law enforcement agencies. It was pointed out that the NDA presents a conflict since the normal duty of members of various teams (library construction, software engineers) at the Joint Technology Center includes knowledge of organism being sequenced.
- 2.4 The chair reported on the progress with the implementation of electronic signatures at TIGR and the enhancement of Forms 108 and 109, a prerequisite for the computerized routing forms.

3. Grant proposal/Project Review

- 3.1 Reviewed Dr. Christopher Town's project entitled "Expression profiling of *Arabidopsis thaliana* hypothetical genes by quantitative RT PCR". The committee determined that the experiments submitted are **exempt** from the NIH Guidelines and recommended that all experiments be performed under **BL1** containment as described in the TIGR Biosafety Manual and in the *NIH Guidelines*.
- 3.2 Reviewed Dr. Claire Fraser's projects (with Dr. Jacques Ravel) entitled
Whole genome sequencing of *Yersinia pestis* Angola Pestoides
Whole genome sequencing of *Yersinia pestis* Orientalis China
Whole genome sequencing of *Yersinia pestis* Pestoides F
Whole genome sequencing of *Yersinia pestis* Orientalis Madagascar
Y. pestis is a Risk Group 3 organism (<http://www.absa.org/riskgroups/Bacteria.html>) and select agent (<http://www.cdc.gov/od/sap/docs/salist.pdf>). No culturing of live organisms is planned at TIGR and only DNA will be received and handled. The committee recommended that library construction be performed under **BL2** containment according to Section III-D-2-a of the NIH Guidelines.
- 3.3 Reviewed Dr. Claire Fraser's project (with Dr. William Nierman) project entitled "Sequencing of *Burkholderia mallei* and *pseudomallei* strains. *B. mallei* and *B. pseudomallei* are Risk Group 3 organisms (<http://www.absa.org/riskgroups/Bacteria.html>) and listed as overlap select agents by HHS/USDA (<http://www.cdc.gov/od/sap/docs/salist.pdf>). No culturing of live organisms is planned at TIGR and only

DNA will be received and handled. The committee recommended that library construction be performed under **BL2** containment according to Section III-D-2-a of the NIH Guidelines.

- 3.4 Reviewed Dr. Malcolm Gardner's project entitled "*Coccidioides immitis (posadasii)* genome sequencing project". *C. immitis* is a Risk Group 3 organism (<http://www.absa.org/riskgroups/Riskgroups-Fungi.html>) and a select agent (<http://www.cdc.gov/od/sap/docs/salist.pdf>). No culturing of live organisms is planned at TIGR and only DNA will be received and handled. The committee recommended that library construction be performed under **BL2** containment in accordance with Section III-D-2-a of the NIH Guidelines.
- 3.5 Reviewed Drs. Peterson and Fleischmann's "Pathogen Functional Genomics Research Center (PFGRC)- Protein Expression" project. No known toxic products will be expressed. No intentional mutations are being produced in the constructs. No altered metabolism. The committee recommended that all experiments be performed under **BL2** containment. The committee also recommended that the principal investigators communicate a detailed plan on how they plan to screen for potential toxicity and biosafety issues.
- 3.6 Reviewed Drs. Peterson and Fleischmann's "PFGRC- Gateway cloning project" project. Since the Gateway Program utilizes a non-expressing cloning vector, only single ORFs are being cloned, and no known toxins are being cloned, most of these cloning experiments can be carried out under BL1 conditions. Since the source organisms for some of the DNA are Risk Group 2 or 3 organisms, the committee recommended that all experiments be performed under **BL2** containment in accordance with Section III-D-2-a of the NIH Guidelines.

4. Other agenda items

- 4.1 Kay Wellman proposed a joint TIGR/VI IBC training session in early March to be offered by Kathryn Harris from the OBA.
- 4.2 Staff counsel Reid Adler and Michael Brown to be contacted for discussion of legal matters pertaining to the handling and implementation of TIGR IBC's recommendations for BSL2 containment at JTC during library construction. Issues under discussion include the need to label the library construction laboratory as a BSL2 lab with a list of all names of organisms for which rDNA is being handled.
- 4.3 Members of the IBC asked to receive copies of the material to review in advance of IBC meetings.

Meeting adjourned at 12:00 noon

THE INSTITUTE FOR GENOMIC RESEARCH INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

<i>TIGR Institutional Biosafety Committee Meeting Overview</i>	
<p>Date: 112204 Start Time: 10:00 AM End Time: 11:30 AM Location: Executive Library</p>	<p>Objective/Desired Outcome:</p> <ol style="list-style-type: none"> 1) Review of pending proposals 2) The OBA inquiry 3) Continued discussions on streamlining IBC proposal review and its integration with grant routing and approval process.
<p>Attendees: Najib El-Sayed, Ph.D. (IBC chair, parasite expert), Elodie Ghedin, Ph.D. (parasite/virus expert), Steven Gill, Ph.D. (bacteriology expert), Hanif Khalak (community representative), Barbara Methé, Ph.D. (bacteriology expert), David Narum, Ph.D. (community representative), Clyde Ragland (biosafety officer) & Chris Town (plant expert). Also present was non-voting member Leslie Bisignano from the Office of Sponsored Projects, and Tinu Akinyemi as the Administrative Assistant</p>	

Meeting Summary

1. The IBC reviewed several proposals pending review at the NIH.

Title: Protective immunity to *P. vivax* preerythrocytic stages

PI: Dr. Ruobing Wang

The IBC reviewed the above mentioned project and determined that the experiments described are exempt from the NIH Guidelines. The Committee did, however, recommend that all experiments be performed under BL2 containment as described in the TIGR Biosafety Manual and in the *NIH Guidelines* (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_G.htm).

Title: Immune response to *P. vivax* in Duffy(-) humans

PI: Dr. Ruobing Wang

The IBC reviewed the above mentioned project and determined that the experiments described are exempt from the NIH Guidelines. The Committee did, however, recommend that all experiments be performed under BL2 containment as described in the TIGR Biosafety Manual and in the *NIH Guidelines* (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_G.htm).

Title: Essential genes in *Burkholderia* biodefense pathogens

PI: Dr. William Nierman

The committee requested that Dr. Nierman provide a better description of the scope of the project within the two collaborating institutes including details about where each of the experiments will be performed.

Title: Identification of T-cell antigens for *Burkholderia mallei* vaccine development

PI: Dr. Ruobing Wang

The committee reviewed the forms submitted in conjunction with this proposal and invited Dr. Wang into the meeting for a few minutes to provide some clarifications. The Committee requested the provision of documentation on type of screen for *B. mallei* in imported horse serum, as well as about the sensitivity of the assays used and the level of experience of personnel at the Australian facility. The IBC communicated this request verbally to Dr. Wang, who will proceed with getting the information should the proposal score well at study section

Title: Sequencing of human Coronavirus strains (MSC 8010k)

PI: Dr. Elodie Ghedin

The IBC reviewed this project and determined that the experiments described are **exempt** from the NIH Guidelines since no DNA cloning will be performed (All sequencing will be performed on PCR product). The Committee did, however, recommend that all experiments be performed under **BL2** containment as described in the TIGR Biosafety Manual and in the *NIH Guidelines* (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_G.htm).

Title: Isolation and Sequencing of Retroviruses from primate blood

PI: Dr. Elodie Ghedin

The IBC determined that the experiments described in this proposal may be performed under **BL2** containment as described in the TIGR Biosafety Manual or in the *NIH Guidelines* (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_G.htm). Because primate blood will be handled, the Committee recommended that all blood samples be treated as if known to be infectious for HIV, HBV, and other blood borne pathogens. A description of the "Universal precautions" to be adopted can be found in the original OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) or on this web site: <http://www.niehs.nih.gov/odhsb/biosafe/univers.htm>.

Meeting Summary (con't)

2. Recap of Sunshine project's allegations and the background of their complaint to the OBA (NIH). Review of OBA's inquiry letter into TIGR's IBC activities and compliance with the *NIH Guidelines*. The IBC chair informed the external IBC members that an inventory was underway to review all research grants and programs at TIGR and determine whether they were reviewed by the TIGR IBC.

3. The committee continued discussions on the implementation of better ways for submission of IBC forms. The lack of an accepted electronic signature protocol at TIGR is still a handicap and will prevent a true integration of Forms 108 and 109 with the grant proposal approval form. Najib will follow up with Michael Brown (TIGR senior counsel) regarding electronic signatures at TIGR. Leslie Bisignano will also discuss with TIGR Chief Financial Officer whether accessing a portion of the database of the Office of Sponsored Projects will be possible for the IBC.

THE INSTITUTE FOR GENOMIC RESEARCH INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING

<i>TIGR Institutional Biosafety Committee Meeting Overview</i>	
<p>Date: 042304 Start Time: 10:00 AM End Time: 11:00 AM Location: Conference Room B</p>	<p>Objective/Desired Outcome:</p> <ol style="list-style-type: none"> 1) Introduction of new IBC members. 2) Review of TIGR forms 108 and 109. 3) Discussion of more streamlined ways for IBC proposal review that is integrated with the new grant routing and approval process.
<p>Attendees: Najib El-Sayed, Ph.D. (IBC chair, parasite expert), Elodie Ghedin, Ph.D. (parasite/virus expert), Steven Gill, Ph.D. (bacteriology expert), Hanif Khalak (community representative), Barbara Methé, Ph.D. (bacteriology expert), David Narum, Ph.D. (community representative), Clyde Ragland (biosafety officer) & Chris Town (plant expert). Also present were non-voting members Benjamin Guthrie (TIGR Department of Sponsored Projects, sitting in for Leslie Bisignano), & Aimee Turner (CFO, TIGR).</p>	

Meeting Summary

1. New members of the TIGR IBC were introduced. They included Drs. Steven Gill and Barbara Methé (microbiology experts), Dr. Christopher Town (plant expert, replacing former member Cathy Whitelaw), and Mr. Hanif Khalak (resident in Rockville and representing the surrounding community).

2. Najib presented recently designed TIGR Forms 108 (**Initial Recombinant DNA (rDNA) Research Classification form**) and 109 (**Recombinant DNA (rDNA) Research Questionnaire and IBC Registration Document**)



TIGR_Form108



TIGR_Form109

Both forms were designed to assist Principal Investigators in the rapid determination of whether suggested experiments are exempt from the NIH guidelines or need a careful and detailed review by the full IBC committee.

a. It was noted that all proposals reviewed to date have been determined to be exempt from the NIH guidelines by the committee chair, following a thorough and time-consuming review of the contents of each proposal and circumventing the need for full committee meetings. A more efficient way of capturing information to determine the status of a proposed project should be implemented.

b. Forms 108 and 109 were pilot tested for the past two months. Najib noted that PI's who submitted those forms were still requiring quite a bit of assistance in the process. Chris Town suggested a yearly training seminar for all faculty and staff scientists.

c. It was decided that form 108 should be modified to capture additional information: i) potential funder or funding source/grant number if project is in progress and ii) abstract and specific aims as they appear on the grant.

3. The committee discussed the implementation of better ways for submission of IBC forms. Currently, forms 108 (and 109 when needed) are submitted to the TIGR IBC by E-mail after retrieving forms located on the human resources internal web site and filling them. We would like to work in the future with TIGR's sponsored project department to:

a. Integrate the IBC approval process with an electronic grant routing sheet. Aimee Turner stated that an electronic signature system should be put in place before they can make their forms electronically fillable.

b. Share a portion of the sponsored projects database. This discussion will await Leslie Bisignano's return from maternity leave.

4. The full TIGR IBC agreed that an internal TIGR IBC subcommittee should continue meeting to further develop forms and processes. The subcommittee will report back to the full IBC at the next meeting.