

9712 Medical Center Drive, Rockville, Maryland 20850  
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<http://www.tigr.org>



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,

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 (PFGR)-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 "PFGR- 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**

<b><i>TIGR Institutional Biosafety Committee Meeting Overview</i></b>	
<b>Date:</b> 112204 <b>Start Time:</b> 10:00 AM <b>End Time:</b> 11:30 AM <b>Location:</b> Executive Library	<b>Objective/Desired Outcome:</b> <ol style="list-style-type: none"><li>1) Review of pending proposals</li><li>2) The OBA inquiry</li><li>3) Continued discussions on streamlining IBC proposal review and its integration with grant routing and approval process.</li></ol>
<b>Attendees:</b> 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	

### ***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](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](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](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](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**

<b><i>TIGR Institutional Biosafety Committee Meeting Overview</i></b>	
<b>Date:</b> 042304 <b>Start Time:</b> 10:00 AM <b>End Time:</b> 11:00 AM <b>Location:</b> Conference Room B	<b>Objective/Desired Outcome:</b> <ol style="list-style-type: none"> <li>1) Introduction of new IBC members.</li> <li>2) Review of TIGR forms 108 and 109.</li> <li>3) Discussion of more streamlined ways for IBC proposal review that is integrated with the new grant routing and approval process.</li> </ol>
<b>Attendees:</b> 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).	

### ***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.



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Mr. Edward Hammond  
Director  
The Sunshine Project  
101 West 6<sup>th</sup> Street, Suite 607  
Austin, TX 78701  
Tel: 512-494-0545

July 26, 2004

Mr. Hammond,

In response to your letter dated June 24, 2004 requesting all minutes of all meetings of the TIGR IBC from January 2001 through the present date, I am attaching the minutes for a meeting held on March 6, 2002. You have already requested and received the minutes for meetings held from June 2003 through June 24, 2004. No other formal meetings were held since the inception of TIGR's IBC.

I would like to note that, as of this date, all the recombinant DNA activity at TIGR have been determined to be exempt from the 'NIH Guidelines for Research Involving Recombinant DNA molecules'. We consider the NIH Office of Biotechnology Activities to be a key partner in our effort to comply with the NIH guidelines and welcome their input should it be required. We work eagerly to ensure that TIGR and its practices are in compliance with the NIH guidelines.

Regards,

A handwritten signature in black ink, appearing to read "Najib M. El-Sayed", written over a horizontal line.

Najib M. El-Sayed, Ph.D.  
Chair, Institutional Biosafety Committee  
Associate Investigator, Parasite Genomics Group  
The Institute for Genomic Research (TIGR), Rockville, MD

cc: Dr. Amy Patterson, NIH Office of Biotechnology Activities

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

<b>TIGR Institutional Biosafety Committee Meeting Overview</b>	
<b>Date:</b> 030602 <b>Start Time:</b> 12:00 PM <b>End Time:</b> 1:00 PM <b>Location:</b> Executive library	<b>Objective/Desired Outcome:</b> 1) Introductions-Lunch. 2) Review of the 'Guidelines'. 3) Review of 2 proposals and discussion of review policy.
<b>Attendees:</b> Najib El-Sayed, Ph.D. (IBC chair, parasite expert), Elodie Ghedin, Ph.D. (parasite/virus expert), Donna Maglott (community representative), David Narum, Ph.D. (community representative), Cathy Whitelaw (plant expert). Also present were non-voting member Leslie Bisignano (TIGR Department of Sponsored Projects) & Robin Buell, Ph.D. ( <i>Ad hoc</i> plant expert replacing Dr. Whitelaw as her proposal is voted on).	

### *Meeting Summary*

1. Members of the TIGR IBC were introduced as they appear on the list of attendees.
2. The 'NIH Guidelines for Research Involving Recombinant DNA molecules' (<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>) were reviewed, including the functions and responsibilities of the IBC.
3. Two TIGR proposals were reviewed. They are entitled A) "A Comparative Genomic Approach to Plant Cell Separation Processes in *Brassica napus* and *Arabidopsis thaliana*" and B) "Functional Analysis of Hypothetical Proteins from *Arabidopsis thaliana* using Full-length cDNAs". The Principal Investigators are Cathy Whitelaw and Christopher Town, respectively. Both proposals were found to be exempt according to Section III-D-5 'Experiments Involving Whole Plants' of the NIH guidelines. The PI's will be notified.
4. The full TIGR IBC agreed that since the large majority of grants and proposals are restricted to sequencing projects leading to the generation of recombinant DNA libraries into standard *E. coli* cloning/sequencing vectors, a review of the proposals by the IBC chair is acceptable when the experiments are determined to be exempt from the guidelines. The sequencing vectors used at TIGR are not designed for expression in prokaryotic or eukaryotic systems. In addition, no known full length toxin clones under any transcriptional regulation are typically produced. As such, sequencing libraries are exempt from the NIH Guidelines for the conduct of research involving recombinant DNA. The TIGR IBC chair will work on methods/forms to help streamline the classification process.

*Journal of Management Inquiry* 18(6)

Author:  Title:

1. The following information is provided under the provisions of the Access to Information Act / Loi sur l'accès à l'information.

1. The first step in the process of identifying a problem is to define the problem. This involves identifying the symptoms of the problem and determining the scope of the problem. Once the problem has been defined, the next step is to identify the causes of the problem. This involves identifying the factors that are contributing to the problem and determining the underlying causes. Once the causes have been identified, the next step is to develop a plan of action. This involves identifying the steps that need to be taken to solve the problem and determining the resources that will be needed to implement the plan. Once a plan of action has been developed, the next step is to implement the plan. This involves carrying out the steps that have been identified in the plan and monitoring the progress of the implementation. Finally, the last step in the process is to evaluate the results of the implementation. This involves determining whether the problem has been solved and whether the resources have been used effectively.

1. The first of the two main parts of the report is a general survey of the situation in the country. It is divided into two main sections: the first deals with the political situation and the second with the economic situation. The first section is divided into three parts: the first part deals with the political situation in the country as a whole, the second part deals with the political situation in the various provinces, and the third part deals with the political situation in the various districts. The second section is divided into two parts: the first part deals with the economic situation in the country as a whole, and the second part deals with the economic situation in the various provinces.



TIGR Form No. 9

9712 Medical Center Drive  
Rockville, MD 20850  
301-838-0200  
301-838-0208 FAX

## FACSIMILE TRANSMITTAL FORM

DATE: 7/26/04TO: Mr. Edward ThomasFAX NO: (302) 494-0545FROM: Dr. Najib El-Sawal

COMMENTS: \_\_\_\_\_

NUMBER OF PAGES (INCLUDING COVER SHEET): 4

The information contained in this facsimile message is privileged and confidential information intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this fax is strictly prohibited. If you have received this fax in error, please immediately notify us by telephone and return the original message to us at the address above via United States Postal Service.

Revised 01/01

9712 Medical Center Drive, Rockville, Maryland 20850

(301) 838-0200

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July 12, 2004

Mr. Edward Hammond  
The Sunshine Project  
101 West 6<sup>th</sup> Street, Suite 607  
Austin, TX 78701

Mr. Hammond:

I am in receipt of your first request for additional TIGR IBC minutes dated June 24, 2004 as well as a second request with the same date but faxed to my attention on July 7, 2004. Due to the July 1st grant submission deadline and the July 4th holiday, I was unable to respond to your request; however, please be advised that I will respond to your request by the COB on Friday, July 23, 2004 and upon my return from an international meeting for which I am currently preparing.

Sincerely,

A handwritten signature in black ink, appearing to read "Najib M. El-Sayed", written over a horizontal line.

Najib M. El-Sayed, Ph.D.  
Chair, Institutional Biosafety Committee  
The Institute for Genomic Research

cc: Dr. Amy Patterson, Director, NIH Office of Biotechnology Activities

9712 Medical Center Drive, Rockville, Maryland 20850

(301) 838-0200

(301) 838-0208 Fax



Mr. Edward Hammond  
Director  
The Sunshine Project  
101 West 6<sup>th</sup> Street, Suite 607  
Austin, TX 78701  
Tel: 512-494-0545

June 22, 2004

Mr. Hammond,

In response to your letter dated May 24<sup>th</sup>, 2004 requesting all minutes of all meetings of the TIGR IBC from June 1, 2003 through the present date, I am attaching the minutes for our single meeting held during that time period.

Regards,

A handwritten signature in blue ink, appearing to read "Najib M. El-Sayed", with a stylized flourish at the end.

Najib M. El-Sayed, Ph.D.  
Chair, Institutional Biosafety Committee  
Associate Investigator, Parasite Genomics Group  
The Institute for Genomic Research (TIGR), Rockville, MD

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

<b><i>TIGR Institutional Biosafety Committee Meeting Overview</i></b>	
<b>Date:</b> 042304 <b>Start Time:</b> 10:00 AM <b>End Time:</b> 11:00 AM <b>Location:</b> Conference Room B	<b>Objective/Desired Outcome:</b> 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.
<b>Attendees:</b> 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).	





TIGR Form # 108  
Last Revised Date: 7/2003  
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*This form must be submitted with the proposal approval form if doing recombinant DNA work*

### Initial Recombinant DNA (rDNA) Research Classification

This information is required to determine the level of review for proposed experiments, based on Federal requirements for research involving rDNA. All research involving rDNA must be reviewed by the IBC, regardless of funding.

For more information on these requirements, please see

[NIH Guidelines for Research Involving Recombinant DNA Molecules](#)

For non-exempt experiments, you will be required to complete an additional form.

Project Title:	
Project Sponsor:	
Principal Investigator:	Laboratory Contact:
Telephone:	Laboratory Telephone:
Laboratory Location:	
List co-investigators or other key personnel:	

1. Does the research involve transfection of rDNA using exempt OR certified host-vector systems (including but not limited to *Escherichia coli* K-12, *Saccharomyces cerevisiae*, *Saccharomyces uvarum*, or any asporogenic *Bacillus subtilis* or asporogenic *Bacillus licheniformis* strain which does not revert to a spore-former with a frequency greater than  $10^{-7}$ )? (see [Section III-F](#) and appendices [A](#), [C](#) and [E](#) of the NIH Guidelines )

YES ☐ NO ☐

2. Does the research involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture (see [Section III-A of NIH Guidelines](#))

YES ☐ NO ☐

3. Does the research involve the deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal to vertebrates at an LD<sub>50</sub> of less than 100 ng / kg body weight (see [Section III-B-1 of NIH Guidelines](#)) ?

YES ☐ NO ☐

4. Does the research involve the deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into one or more human research participants (see [Section III-C of NIH Guidelines](#)) ?

YES ☐ NO ☐



TIGR Form # 108  
Last Revised Date: 7/2003  
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5. Does the research involve DNA from Risk Groups 2, 3, 4, or restricted organisms or cells known to be infected with these agents (*see* [Section III-D-1, III-D-2](#) and [Appendix B of NIH Guidelines](#)) ?

YES ☐ NO ☐

6. Does the vector used contain eukaryotic viral DNA (other than CMV promoter and SV40 poly A site)?

YES ☐ NO ☐

7. Does the research involve the use of any recombinant plasmids/vectors/viruses in whole animals (*see* [Section III-D-4 of NIH Guidelines](#))?

YES ☐ NO ☐

8. Does the research involve the use of any recombinant plasmids/vectors/viruses in whole plants (*see* [Section III-D-5 of NIH Guidelines](#))?

YES ☐ NO ☐

9. Does the research involve experiments involving more than 10 liters of culture (*see* [Section III-D-6 of NIH Guidelines](#))?

YES ☐ NO ☐

10. Are other experiments proposed involving rDNA not covered here?

YES ☐ NO ☐

Comment:

11. Do you have prior IBC approval (or exemption) for IDENTICAL rDNA work?

YES ☐ NO ☐

If yes, give IBC registration #\_\_\_\_\_ (or submit copy of approval or exemption letter).  
If rDNA experiments have been modified, you must submit these revisions to the IBC or complete a new rDNA research questionnaire if necessary.



TIGR Form #109  
 Last Revised Date: 7/2003  
 Page 1 of 3

## Recombinant DNA (rDNA) Research Questionnaire and IBC Registration Document

All research involving rDNA must be reviewed by the IBC, regardless of funding. For more information on these requirements, please see

[NIH Guidelines for Research Involving Recombinant DNA Molecules](#)

(Please answer questions completely – Use additional space as necessary)

Principal Investigator Last Name, First Name		Years of laboratory experience relevant to this agent(s)	
Telephone Number	Email Address	Laboratory Contact	
Project Title			Project Sponsor
Additional research personnel to work with agent(s) on this project		Position	Years of relevant experience

Note: You may be asked to provide additional information concerning facilities and procedures for minimizing biosafety risk factors.

For questions, contact the TIGR IBC chair at (301)838-3525, or the TIGR Biosafety Officer at (301)838-3518. Return signed original to IBC chair or biosafety officer and email to: [ibc@tigr.org](mailto:ibc@tigr.org)

### Brief Project Summary (specifically address the use of recombinant DNA)

Please use language appropriate for a scientific academician working in an unrelated field





TIGR Form #109  
Last Revised Date: 7/2003  
Page 3 of 3

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Host

14. For *in vitro* use discuss host cells targeted (bacterial, eukaryotic, species).
  15. For *in vivo* use discuss host species and target organs or systems.
  16. Are helper viruses present in the host, which may lead to replication-competency for the recombinant construct? Discuss.
  17. For whole animals, could there be an adverse physiological impact? Discuss.
  18. Are there biohazard implications including potential exposure to staff and animal colonies? Discuss. Specifically address the potential for shedding of the virus *in vivo* from the animal host.
  19. Describe the containment facilities where these experiments (both *in vitro* and *in vivo*) will take place.
- 

Assurance

*I will abide by the NIH Guidelines for Research Involving Recombinant DNA Molecules and the CDC Guidelines for Biosafety in Microbiological and Biomedical Laboratories.*

*I will maintain a current record of any transfer of recombinant DNA, or vectors or host strains containing recombinant DNA, or infectious agents between investigators at this or other institutions.*

*I will agree that prior to engaging in non-exempt recombinant DNA research or research involving known or potential pathogens, all laboratory personnel will receive instruction in microbiological practices, including aseptic techniques, and in the biology and possible infection symptoms associated with the organisms to be used in the experiments.*

*I agree to send a revised project description to the Institutional Biosafety Committee if changes are made to this protocol that may alter the status of containment required or upon grant renewal.*

---

Principal Investigator

Signature

Date

---

Print name (PI)

### *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.

Envelope-to: hammond@underdog02.underdoghosting.com  
Subject: Request for IBC minutes  
Date: Wed, 9 Jun 2004 17:29:08 -0400  
Thread-Topic: Request for IBC minutes  
Thread-Index: AcROaMxKiaKJ29dGTR2oXifP9cs8Zg==  
From: "El-Sayed, Najib" <nelsayed@tigr.org>  
To: <hammond@sunshine-project.org>  
X-Spam-Checker-Version: SpamAssassin 2.62 (2004-01-11) on  
underdog02.underdoghosting.com  
X-Spam-Status: No, hits=0.8 required=5.0 tests=HTML\_30\_40,HTML\_MESSAGE  
autolearn=no version=2.62  
X-Spam-Level:

Mr. Hammond --

I am the chair of the Institutional Biosafety Committee at TIGR and I received yesterday a forwarded certified letter dated May 24th, 2004 requesting the minutes of TIGR's IBC for the past year by June 8th, 2004. I believe the records that you have received from OBA are not up to date as I have been chairing this Committee for over 2 years now and have notified the OBA.

I am quite happy to provide your organization with our IBC minutes but unfortunately cannot do so on such short notice and will be able to comply by the end of June.

Regards,

Najib M. El-Sayed, Ph.D.

Chair, Institutional Biosafety Committee  
The Institute for Genomic Research  
9712 Medical Center Drive, Rockville, MD 20850  
+1 (301) 795-7525 <<<<< Please note: NEW PHONE NUMBER  
+1 (301) 838-0208 (fax)



THE INSTITUTE FOR GENOMIC RESEARCH

TIGR Form No. 9

9712 Medical Center Drive  
Rockville, MD 20850  
301-838-0200  
301-838-0208 FAX

## FACSIMILE TRANSMITTAL FORM

DATE:

7/13/04

TO:

Mr. Hammond

FAX NO:

512-494-0545

FROM:

Dr. Najib El-Sayed

COMMENTS:

NUMBER OF PAGES (INCLUDING COVER SHEET):

2

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Revised 01/01

# the sunshine project

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24 June 2004

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Dr. Najib M. El-Sayed  
Chair, Institutional Biosafety Committee  
The Institute for Genomic Research  
9712 Medical Center Drive  
Rockville MD 20850

By fax: (301) 838-0208

Dear Dr. El-Sayed,

Thank you for your letter of 22 June in which you provide minutes from a meeting of The Institute for Genomic Research Institutional Biosafety Committee (TIGR IBC). It took three requests to hear back from you; but certified mail finally did the trick, although it involved additional cost for me. I hope that, this time, you will be responsive to a fax. I am sending it to the number on your letterhead.

I have reviewed the minutes of the TIGR IBC that you have provided. You have provided minutes of one meeting, that of 23 April 2004. I requested "*All minutes of all meetings of the The Institute for Genomic Research Institutional Biosafety Committee from 1 June 2003 through the present date.*"

Thus, it appears that the TIGR IBC meets less than once per year. I find this to be surprising, considering the type and scale of recombinant DNA activity at TIGR. I appreciate that some rDNA activities at TIGR may be exempt from full committee review, however, many are not. I attach one such example, the project "Regulation of *Burkholderia mallei* virulence genes", NIAID grant 1R01AI056006-01.

I am additionally concerned by the fact that your minutes reflect that the TIGR IBC, when it did actually meet, limited its activity to discussion of the format of its own paperwork. It did not conduct any review of research protocols nor evaluation of the state of laboratories, nor protocol renewals, nor discussion of adverse events, etc.

*Therefore, pursuant to the NIH Guidelines, the Sunshine Project hereby requests all minutes of all meetings of the TIGR IBC from 1 January 2001 through the present date.*

I look forward to your prompt reply.

Sincerely,



Edward Hammond

cc: Dr. Amy Patterson, Director, NIH Office of Biotechnology Activities



THE INFORMATION CONTAINED  
HEREIN IS UNCLASSIFIED  
DATE 10/10/2001 BY 60322 UCBAW

Page 10 of 10

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