

Environmental Health and Safety Office

February 4, 2004

Mr. Edward H. Hammond
Director
The sunshine project
101 West 6th Street
Suite 607
Austin TX 78701

Dear Mr. Hammond

We are in receipt of your facsimile requesting minutes of two most recent meeting of the University of Hawaii Institutional Biosafety Committee.

As our written policy of request must be a formal written request with an original signature. Please forward you request to me, Chair, UH Instructional Biosafety Committee at the address above.

It should also be noted that the cost of photocopying may be assessed.

Thank you,



James T. Douglas, Ph.D.
Chair
UH Institutional Biosafety Committee

the sunshine project

101 West 6th Street, Suite 607 Austin TX 78701 USA

Tel/Fax: +1 512 494 0545

<http://www.sunshine-project.org>

9 March 2004

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Chee Yoke Ling
Kuala Lumpur, Malaysia

Julian Perry Robinson
Brighton, United Kingdom

Tewolde Berhan Gebre Egziabher
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James T. Douglas
Chair, UH IBC
University of Hawaii at Manoa
2040 East-West Road
Honolulu HI 96822

By fax: (808) 956-3205

*5/12/04 by fax of
hand copy*

Dear Dr. Douglas,

Pursuant to the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section IV-B-2-a-(7),³³⁴ the Sunshine Project hereby requests copies of the Minutes of the two (2) most recent meetings of the University of Hawaii at Manoa Institutional Biosafety Committee (IBC).

Please send the Minutes to the address above. I request that you please mail your reply immediately.

This letter is sent to you as part of a national survey of compliance with the public access provisions of the NIH Guidelines.

When you respond, I would appreciate your taking the time to answer the following question (please circle one):

University of Hawaii at Manoa IS / IS NOT registered to handle select agents.

Please feel free to attach any additional explanatory materials that you feel are appropriate.

Thank you very much for your attention to this request.

Sincerely,

Edward H. Hammond
Director

³³⁴ *Section IV-B-2-a-(7). Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes...*

the sunshine project

101 West 6th Street, Suite 607 Austin TX 78701 USA

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16 June 2004

ADVISORY COMMITTEE

Ignacio Chapela
Berkeley, United States

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Kuala Lumpur, Malaysia

Julian Perry Robinson
Brighton, United Kingdom

Tewolde Berhan Gebre Egziabher
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Dr. James T. Douglas, Chair
Institutional Biosafety Committee
Environmental Health and Safety Office
University of Hawaii at Manoa
2040 East-West Rd
Honolulu HI 9622

By US Mail, fax: 808-956-3205, e-mail (biosafe@hawaii.edu, jdouglas@hawaii.edu)

Dear Dr. Douglas,

On 29 January I faxed the University of Hawaii at Manoa to request minutes of meetings of its Institutional Biosafety Committee (UH IBC).

In a letter dated 4 February you replied to my request by insisting that "*As our written policy of request most [sic] be a formal written request with an original signature. [sic] Please forward you [sic] request to me, Chair, UH Instructional [sic] Biosafety Committee at the address above.*"

Personally, I found your insistence on an original signature pointless and nonsensical considering that the records must be provided to any member of the public upon request, however, in the interest of moving forward with my survey, on 9 March I sent you another request for UH IBC minutes. The second request was sent by fax and by US mail, so that you could have "an original signature".

You have not replied to the second request. Somehow, given your initial letter, I suspect that you will say that you never received the second request.

Let's please dispense with the mindless bureaucracy – or is it mindful bureaucracy to make my request difficult? UH must produce the minutes. You know that I have requested them – three times now – and you know where to send them, electronically or by mail. Please do so immediately.

Moreover, by this letter, fax, and e-mail, I extend the request as follows:

Pursuant to the NIH Guidelines, the Sunshine Project here by requests all minutes of all meetings of the UH IBC, from 1 September 2001 through the present.

Sincerely,

Edward Hammond
Director

cc: Allan Shipp, NIH Office of Biotechnology Activities (by e-mail)
Members of the UH IBC (by e-mail)

*original sent
US mail*

UNIVERSITY OF HAWAII AT MANOA
Environmental Health and Safety Office

Institutional Biosafety Committee

June 17, 2004

Mr. Edward Hammond
Director
The Sunshine Project
101 West Sixth Street, Suite 607
Austin TX 78701

Dear Mr. Hammond,

The University of Hawaii's Institutional Biosafety Committee (IBC) is in receipt of your request (1/29 facsimile, 2/4 letter, 3/9 facsimile and 4/16 facsimile) for two recent IBC minutes.

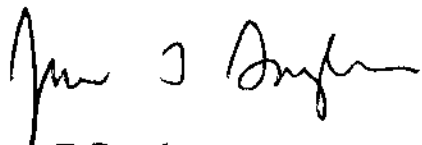
As we are state agencies, we have policies in which to follow. Currently, we have advised our UH Legal Counsel for their opinion on this request and they have not made a determination.

However, as stipulated by recent advisory form the NIH Office of Biotechnology Activities, we will provide you copies.

CDC Select Agent Program has advise us not to release site-specific or identifying information associated with 42 CFR Part 73 to the public. Also waiting, advise from USDA-APHIS. So, at this time we cannot confirm or deny whether the University of Hawaii has or has no Select Agents. This is not a purview of the NIH guidelines.

Please find attach the last two most recent IBC minutes, dated 11/20/03 and 3/27/04. As a reply to our e-mail response of 6/16, the UH IBC has not met in the recent months. All research protocol is exempt under NIH guidelines.

Aloha



James T. Douglas
Chair
UH-Institutional Biosafety Committee

IBC Minutes 11/20/03 1:30 p.m.

Meeting with Monsanto

- I Attendance: J. Douglas, D. Christopher, J. Berestecky, R. Cann, L. Wong, F. Perkins
- II. Minutes of 3/27/03 approved.
- III. Meeting with Mr. Martin D. Lemon, Manager
Biotechnology and Environmental Science,
Monsanto Company
 - A. IBC supports collaborative research
 - B. IBC expressed their feeling that all collaboration with UH researchers must have an internal review and approval prior to field testing.
 - C. Mr. Lemon reiterated his company's policy on compliance.
- IV. Meeting adjourned at 3:00 p.m.

IBC Minutes 3/27/04 2:30 p.m.
Pre-Commercialization/Commercialization

- I. Attendance: J. Douglas, D. Christopher, J. Berestecky, R. Cann, J. Scott, L. Wong, F. Perkins, R. Manshardt, R. Takekawa, N. Reimer, P. Sun, and R. Havre
- II. Minutes of 10/17/02 – approved
- III. Discussion on Pre-Commercialization and Commercialization of recombinant technology.
 - A. Hubert Olipares briefed IBC members on NIH, USDA-APHIS, FDA, EPA, State (Dept. of Health and Dept. of Agriculture) and UH policies (OTTED, UH Relations, and VPRGE).
 - B. Richard Manshardt explained his needed support from IBC to commercialized r-papaya.
- III. It is concluded that the PI is the responsible party to ensure compliance with all mandates. IBC will ensure that PI is made aware of these requirements.
- IV. Meeting adjourned at 4:15 p.m.

UNIVERSITY OF HAWAII AT MĀNOA

Environmental Health and Safety Office

Institutional Biosafety Committee Meeting

DATE: Tuesday, April 12, 2005
LOCATION: Snyder Hall 208, Microbiology Conference Room
TIME: 2:30 p.m.

Members Present: Douglas, Scott, Christopher, Cann, Perkins, Wong, and Olipares
Members Absent: Meeks, Berestecky (excused), Harrison, Schuilli (excused), and Kondo (excused).

A. IBC Policies

1. A review of the IBC responsibilities, non-disclosure statement, sensitive/confidential information, UARC/Classified research, Bioprospecting, Stem Cells and Bio-pharming policies was discussed. Policies were detailed on the UH Biosafety Webpage

Majority committee approved IBC policies on above subject matters

- 2 Further discussion was brought up on exempted experiments and authorization of protocols.

As a review: protocols are submitted to the IBC via a BSP-1 or BSP-3 form. A BSP-3 form is for recombinant activities. No protocol are exempt under UH policies. All protocol is reviewed. The Biosafety Officer authorizes any "low risk" protocol. The full committee takes up Moderate-risk" to "High-risk" protocols. Typically, "low risk" is protocols are of risk group 2 or less. All protocols are either authorized as either: (a) Approved, (b) Disapproved or (b) Approved with Conditions. A letter of authorization is attached to the signed copy of the protocol form.

All protocols are assigned an accession number and logged into the Biosafety Program's running Registry. All protocols (Principal Investigators' name, location, and title), being reviewed is considered confidential or proprietary. Any individual that would request information must go through the Designated Institutional Official.

B. Recombinant Activities

Principle Investigators have not produced final documents. All protocols for review will be acted upon on next scheduled meeting.

No action taken

IBC Meeting Minutes
April 12, 2005
Page 2

C. BSL3/ABSL3

a. Kakaako

Schedule for occupancy of the Research building has been moved to early October 2005.

b. Leahi Renovation

Renovation of facility has been drafted. Facility will increase to two suites.

c. Regional Biosafety Laboratory

Preliminary rating score was high.

d. Microbiology

A meeting has been scheduled with Facilities Management

D. Biosafety

a. Dr. Patrick Fu.

Issues of registration and import has been resolved

b. USDA

USDA issued final certification

c. Security Drill

New final rules require annual security and biosafety drills.

d. Movement of Kakaako

All known PI have been advised on proper movement of biological commodities and decontamination of equipments.

IBC Meeting Minutes
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E. Miscellaneous

a. Requested Meeting with HDOA.

Scheduled for Tuesday, May 24, 2005 at 2:00 p.m.

b. Legislation and retribution with House Bill 563.

Inaccuracies with testimony of House Bill 563. HDOA would like to discuss at our scheduled meeting.

c. Chronicle of Higher Education

Dr. Perkins and myself have been interviewed on Sunshine Group and our IBC. Article has been published on Friday, April 30, 2005.

Meeting adjourned at 5:00 p.m.

Institutional Biosafety Committee Meeting

DATE: Tuesday, May 24, 2005

LOCATION: EHSO Classroom (2040 East-West Road)

TIME: 2:30 p.m.

Members Present: Douglas, Christopher, Scott, Cann, Perkisn, Berestecky

Members Absent: Takekawa, Kondo (excused), Schulli (excused), Wong (excused), and Meeks.

A. Call to Order: 2:35 p.m.

B. Approval of Tuesday, April 12, 2005 minutes

Amended minor grammatical changes, Minutes approved.

C. IBC Policies

Request to have a member of the Native Hawaiian Community as part of the IBC.

Discussed and recommend to special interest group.

D. Review of Protocols:

DIO called meeting into Executive Session - Pages 2-5 contains information identified as intellectual property and considered protected by Executive Session Order.

Exempted Protocols:

91A0205G, 245A0405G, 80A0205G, 81A0205G, 161B0305G, 134E0305G, 259A0405G, 95A0205G, 85A0205G, 69A0205G, 132B0305G, 3710105G, 61A0205G, 125A0205G, 103D0205G, 107B0205G, 77A0205G, 172A0305G, 82A0205G, 63A0205G, 158A0305G, 182A0305G, 203A0405G, 195A0305G, 15B0105G, 243A0405G, 248A0405G, 51B0105G, 03D0105G, 114B0205G, 106B0205G, 275A0505G, 89A0205G, 220A0405G, 234B0405G, 235A0405G, 272A0505G, 241A0405G, 255A0405G, 254A0405G, 268B0405G, 256B0405G.

Approved

Non-Exempted

90A0205G, 50B0105G, 24A0105G, 140B0305G, 23A0105G, 186A0305G, 167A0305G, 45A0105G, 210A0405G, 206A0405G, 55A0105G, 219A0405G, 273B0505G.

Discussed and approved

Deferred

241A0405G (see deferral memo as attached)

E. High Containment Facilities

1. RBL

- a. UH has received a good score for the grant. UH team is traveling to NIH at the end of June to answer final questions.
- b. Location has not been finalized.
- c. With increase usage of agents, request that the RBL be contracted for day to day operations. Need a staff for compliance issues.

2. Snyder

- a. Merrick designed the conceptual drawings.
- b. USDA was asked to interpret the minimum construction requirements. As notified by Dr. Monica Brown, no shower of supply HEPA needed. However, requested to leave it in.

3. Leahi

- a. Awaiting final blue-prints.

4. Astrobiology/Cosmochemistry

- a. NASA to coordinate efforts to build a high containment laboratory for the Mars sample to arrive in 2017.

F. Biosafety

G. Miscellaneous

Institutional Biosafety Committee Meeting

DATE: Thursday, January 12, 2006

LOCATION: EHSO Classroom (2040 East-West Road)

TIME: 1:30 pm

MEMBERS PRESENT: Douglas (Chair), Christopher (Vice-Chair), Harrison, Seaver, Wong, Cann, Perkins, Sciulli, Olipares (non-voting)

MEMBERS ABSENT: Takekawa, Kondo, Meeks, Scott, Berestecky

Call to Order: 1:35 pm

1. IBC POLICY

A. Definition of Quorum

After discussion among IBC members, Dr. Perkins made a motion that a quorum for the IBC Committee Meeting be defined as greater than 50% of voting members are present. This motion was approved by all voting members.

B. Appointments to IBC

- (1) After discussion among IBC members, there was a motion by Dr. Perkins to designate that the Director of the Environmental Health and Safety Office be a voting member of the IBC. The motion passed unanimously.
- (2) After much discussion, Dr. Douglas made a motion that the position of Biosafety Officer, which is currently held by Hubert Olipares, remains a non-voting member of the IBC committee. The committee unanimously approved this motion to insure that this position will continue in an objective advisory capacity.

C. Use of Alternates

Dr. Perkins made a motion that encourages committee members to recommend an alternate to fill in when they are unable to attend IBC meetings. If IBC committee member chooses to nominate an alternate, they would forward candidate information to either Hubert Olipares or Dr. Perkins. Individuals would undergo a review process and qualified candidates would be recommended to VP for Research for appointment. Alternates would also undergo training. This motion passed with all affirmative votes.

D. New Protocol Review Policy

A new system was discussed that would have the Biosafety Officer review all protocols, classifying them into 2 categories: 1) exempted or 2) regulated. The executive members (Douglas, Perkins, and Olipares) would review exempt protocols and make a recommendation to the full committee. The full committee will receive information on exempted protocols via email. Any concerns (flagged protocols) should be addressed back (via email) to the subcommittee for clarification. Executive committee members would also be prepared to address questions by other IBC committee members during IBC committee meetings prior to voting. Regulated protocols would be sent to a subcommittee, consisting of 3 IBC members selected by the Chair on the basis of their expertise. The subcommittee would review and present a summary of each regulated protocol to the full committee for action.

Action: The committee decided that it would not vote on implementing a new review policy, but would try this system over the coming month(s) to see if it works to everyone's satisfaction. Karen Quinn will forward the list of January's protocols to committee members sometime in February.

2. EXECUTIVE SESSION:

The Chair called meeting into Executive Session to review protocols.

After discussion, Dr. Harrison made a motion that the following actions be taken on protocols listed:

EXEMPTED AUTHORIZED:

287A0505G, 293A0505G, 307F0505G, 310A0505G, 329A0605G, 338B0605G, 339A0605G, 340A0605G, 344A0605G, 350A0605G, 359A0605G, 362A0605G, 363A0605G, 365A0605G, 371A0605G, 375A0605G, 377A0605G, 378A0605G, 385A0605G, 396C0605G, 397P0605G, 401A0605G, 402A0605G, 406A0605G, 414A0605G, 415A0605G, 422A0605G, 428D0705G, 459D0705G, 469A0705G, 472A0705G, 473A0705G, 476A0705G, 477A0705G, 489A0705G, 497A0705G, 511C0805G, 515A0805G, 522A0705G, 527A0805G, 528A0805G, 529N0805G, 567B0805G, 570A0805G, 573E0805G, 579E0805G, 583D0805G, 597A0905G, 598A0805G, 628D0905G, 630A0905G, 631C0905G, 633A0905G, 634B0905G, 635D0905G, 640A0905G, 642B0905G, 647B0905G, 662C0905G, 667E0907G, 668H0905G, 680A0905G, 684B1005G, 700D1005G, 707D1005G, 711H1005G, 728B1005G, 751B1005G, 753B1005G, 754B1005G, 758D1005G, 765D1105G, 775A1105G, 776B1105G, 793H1105G, 797A1105G, 803F1105G, 806A1105G, 823C1105G, 837A1205G, 859B1205G, 869B1205G

REGULATED AUTHORIZED:

275A0505G, 285A0505G, 308F0505G, 316A0505G, 319A0505G, 334A0605G
335A0605G, 351A0605G, 352A0605G, 353A0605G, 354A0605G, 360A0605G,
382A0605G, 384A0605G, 386A0605G, 419A0605G, 427B0705G, 445A0705G,
450A0705G, 452A0705G, 461C0705G, 463D0705G, 468C0705G, 488A0705G,
571A0805G, 581C0805G, 648A0905G, 678B0905G, 696A1005G, 769A1105G,
784Q1105G, 772A1105G
840B1205G

REGULATED CONDITIONALLY AUTHORIZED:

460C0705G

REGULATED DEFERRED:

322A0505G, 364A0605G

Committee members voted unanimously to pass this motion.

3. FEBRUARY IBC COMMITTEE MEETING WILL BE ON WEDNESDAY,
FEBRUARY 22, 2006 IN THE EHSO CLASSROOM AT 130PM.

Institutional Biosafety Committee Agenda

Date: Wednesday, February 22, 2005 at 1:30 PM
Location: Medical Education Building Rm. 202 (MEB "Access Grid")
651 Ilalo Street Honolulu HI

1:30 PM Tour of ABSL3/BSL3 (please dress comfortably)

2:30 PM IBC meeting

1. Call to order
2. Approval of January 12, 2006 minutes
3. Policy Discussions
 - a. Recent appointment of EHSO Director to IBC as voting member
 - b. Alternate Members
 - c. Subcommittees
 - d. Protocol Review Process
 - e. House Bill 563 – Microorganism Import
 - f. House Bill 3046 – Biological Diversity
4. Executive Session
 - a. Authorization of BSL3/ABSL3
 - b. Protocol Review
 - c. Review previous conditionally approved protocols

4:00 PM Adjourn

**Institutional Biosafety Committee Meeting
February 22, 2006**

MEMBERS PRESENT: Douglas (Chair), Harrison, Scott, Berestecky, Seaver, Meeks, Seifried (Alternate for Cann), Porter (alternate for Christopher), Perkins, Sciulli, Takekawa Olipares (non-voting)

MEMBERS ABSENT: Kondo (present for Tour), Wong (excused)

1. Call to Order: 3:00 PM following tour of Kakaako facilities
2. Approval of January 12, 2006 minutes – A motion to accept the minutes was made by Dr. Harrison and seconded by Dr. Perkins and passed unanimously.
3. IBC POLICY

A. Dr. Douglas reported that there had been 2 Executive IBC meeting where protocols were reviewed to make sure they were assigned properly into either a regulated or an exempted category. Each protocol was discussed and recommendation to either authorize, defer, or conditionally approve were made by Executive IBC members. Regulated protocols were assigned to subcommittees that would give a summary and recommendation to the full committee. Spreadsheets summarizing all recommendations, derived from the 1/18/06 and 2/15/06 Executive IBC meetings, were forwarded to all IBC members.

B. A discussion regarding the need for the position of the EHSO Director (Mr. Roy Takekawa) to continue in an objective advisory capacity only and thus being a non-voting member of the IBC.

Action: A motion was made by Dr. Harrison and seconded by Ms. Sciulli to make the position of EHSO Director a nonvoting member. This motion was unanimously passed.

Dr. Seifried left the meeting at this point, but a quorum remained so the meeting continued.

C. Subcommittees – Dr. Douglas talked about the need to appoint a point of contact (POC) within each subcommittee to take the lead. The Executive Committee will compose a list of subcommittee members based on their expertise, these members will be asked to serve and a POC will be designated after their acceptance. It was agreed that more information needed to be provided to the subcommittees. There was also a discussion regarding going outside the Committee to get expertise if needed and the need to have them sign confidentiality agreement to review protocols. It was concluded that experts would be consulted when needed.

D. House Bill 3046 is off the table according to Dr. Harrison.

E. House Bill 563 – Dr. Harrison stated that this bill shifts the burden to IBC from Department of Agriculture with no mention of funding. Dr. Harrison will not support this bill unless provisions for funding and shared liability are addressed.

4. Authorization of ABSL3/BSL3 facilities

Discussion:

- A. There was a discussion regarding the commissioning report done by Indoor Air Professionals. Mr. Olipares reported that this company has a lot of experience in performing this type of testing and certification. Mr. Olipares also explained that the IBC was the authorizing body for the ABSL3/BSL3 facilities as required by the USDA.
- B. Dr. Harrison took notes during the tour of the facilities and recommended that he give his notes to Ms. Quinn who records the meeting minutes to combine with her notes of the tour to be disseminated to the IBC members. EHSO will address those concerns and report back to the committee.
- C. There was a discussion regarding the pathway for transport of microorganisms between the ABSL3 and BSL3 facilities. The original plan called for pass through between facilities. Committee members would like to know why and who took this out. Other questions that were raised: Is it feasible to create another hole to allow pass through? Why wasn't the IBC notified when the plan changed to not include a pass through?
- D. Decontamination procedures were discussed. Dr. Harrison asked why the doors couldn't be reversed and why the door closing apparatus hadn't been placed on the other side. Mr. Olipares stated that codes require that the doors open inward. Mr. Takekawa stated that when decontamination is done the pressure (flow) reverses. This is noted in the report from Indoor Air Professionals.
- E. The committee strongly feels that there needs to be unannounced spot checks by independent agents to ensure laboratory compliance with Standard Operating Procedures. Mr. Takekawa announced that EHSO is hiring another individual to bring a total of two totally dedicated EHSO hires to work exclusively at Kakaako. These individuals will be doing compliance audits and the results of those audits will be presented to the IBC.

Action:

It was decided that deferring this approval would not hold up work due to the fact that other permits are needed before work begins. Also, the IACUC has not yet begun to look at this and their approval is needed as well. It was pointed out by Mr. Olipares that the principal investigators involved are actually imposing stricter standards than required by government regulations for the type of work. Mr. Olipares has been working closely with the personnel involved.

A motion to defer the approval of the ABSL3/BSL3 facilities was made by Dr. Scott and seconded by Dr. Harrison. A vote was called and there were 8 votes to approve the motion with Dr. Perkins and Mr. Takekawa abstaining.

5. Review of protocols:

Chair calls for Executive Session – pages 4-6 contain information identified as intellectual property and are considered protected by Executive Session Order.

Regulated: 05F0106G and 84A0106G were approved.

Regulated: 61B0106G was conditionally approval.

Regulated: 62D0106G, 105D0106G, 106D0106G were deferred.

Exempted: 01A0106G, 04E0106G, 10A0106G, 11B0106G, 12A0106G, 13B0106G, 15E0105G, 16E0106G, 44F0106G, 47E0106G, 48E0106G, 49E0106G, 60B0106G 63A0106G, 65A0106G, 66E0106G, 90A0106G, 91A0106G, 92A0106G, 93A0106G, 94B0106G, 95B0106G, 96B0106G, 97B0106G, 98B0106G, 99A0106G, 103D0106G, 104D0106G 124H0206G, 125H0206G, 127B0206G, 129A0206G, 130B0206G, 137E0206G, 138A0206G, 139D0206G, 140D0206G, 141A0206G, 143A0206G, 146B0206G, 147B0206G, 148A0206G, 149A0206G, 150A0206G, 731D1005G, 755A1005G, 757A1005G were approved.

6. Adjournment: The meeting was adjourned at 5:30 PM.

Attachments