the sunshine project

Mandate for Failure

The State of Institutional Biosafety Committees in an Age of Biological Weapons Research

Results and Recommendations of the Sunshine Project Survey of Institutional Biosafety Committees

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I ABOUT THIS REPORT

This report on the transparency and operation of Institutional Biosafety Committee (IBCs) is the result of an eight-month survey involving 390 committees across the United States. Historically, IBCs have the responsibility, at the institution level, to protect human health and the environment from the risks of biotechnology research. Now, the mandate of IBCs is expanding to include biological weapons research.

The US does not have comprehensive laboratory safety law, thus, the IBCs operate under non-binding guidelines managed by the US National Institutes of Health. Because of the manifest public interest in ensuring the safety of biotechnology research, the guidelines contain provisions for public access to IBC records, including the minutes of IBC meetings. This survey requested meeting minutes from 390 IBCs and evaluated the response.

Since 2001, the US biodefense program has dramatically increased the scope and volume of biological weapons research, bringing new and expanded bioweapons programs to scores of laboratories.[1] Risks associated with this research, such as accidental releases, proliferation, and domestic terrorism are widely acknowledged.

In its 2003 report *Biotechnology Research in an Age of Terrorism*,[2] the National Academies of Science (NAS) recommended that IBCs be given a new "biosecurity" mandate to oversee the conduct of dual-use research with biological weapons agents. That is, NAS said that IBCs should form the government's front line of defense to prevent biological weapons research from going awry. That recommendation prompted this survey of IBCs and this report, whose subtitle *The State of Institutional Biosafety Committees in an Age of Biological Weapons Research*, refers back to the NAS study.

In March 2004, after this survey had begun, the Bush administration implemented the National Academies' recommendation. It established the National Science Advisory Board on Biosecurity (NSABB), managed by the same NIH office that supervises IBCs. The NSABB will flesh out the details of how the committees are to fulfill their new biological weapons mandate.[3]

Thus, this study comes at a time in which IBCs are undergoing a dramatic transition. The uncertainties provoked in the IBC system by fears of bioterrorism, the expansion of biodefense research into new locations and, particularly, increased work with live biological weapons agents, has been unsettling for many of the safety professionals who handle the daily business of IBCs. The biosafety officer of a major biomedical research university with new programs on biological weapons agents told the survey:

> "*Our profession (rightly or wrongly) has been caught in the middle of a huge collision for the past few years and, frankly, we are all exhausted, confused, and just plain fed up. We'd like to go back to biosafety, which we understand and, for the most part, really love to do.*"[4]

Such disorientation and exasperation at the effects of expanded biological weapons research are sentiments widely shared among biosafety professionals. Responding to the suggestion that the NSABB would impose significant new responsibilities on IBCs, the safety director of another major research university gasped, "*Nobody wants the feds to do that!*"[5] But with the establishment of the NSABB, construction of new

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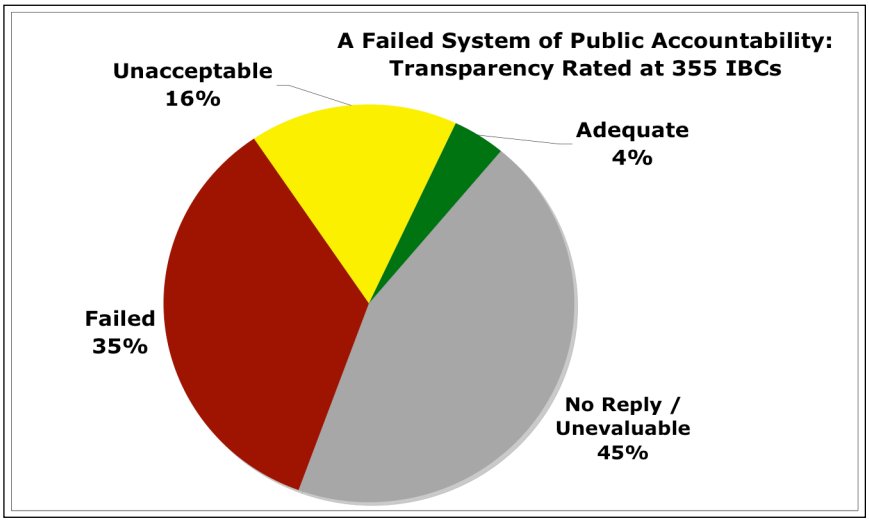
[1] See *Map of High Containment and Other Facilities of the US Biodefense Program*, URL: http://www.sunshine-project.org/biodefense/
[2] Also called the "Fink Report", URL: http://www.nap.edu/books/0309089778/html/
[3] NSABB online: http://www.biosecurityboard.gov.
[4] Personal communication with the biological safety officer of a private university in the South.
[5] Personal communication with the health and safety director of a private university in the West.

laboratories, and large biodefense budgets likely for the foreseeable future, a return to more straightforward times is unlikely - although the people that run IBCs have been poorly informed about their pivotal new responsibilities.

Until this survey, it was an open question if the IBC system was in a state to be able to effectively absorb its new charge. Adequate review of dual-use research is, in many respects, a far greater challenge than IBCs' existing mandate. No longer will the committees be limited to the mechanistic side of biosafety – questions such as *"Is the disinfectant solution the right kind to use?"* or *"Does this agent need level two or level three containment according to the manual?"* Now, IBCs must grapple with a variety of more vexing questions that cannot be reduced to standard operating procedures, such as "*Might this research result in a discovery that could be abused in weapons research? And, if so, under what conditions do we proceed, if at all?"*

In addition to IBCs new role in US research on biological weapons agents, another important context of this study is the failure of negotiations to strengthen the Biological Weapons Convention. Particularly in the absence of a declaration and verification regime under that treaty, blocked by the Bush administration in 2001, the transparency of US research on biological weapons has important ramifications for global peace and security. The US is the world leader in biotechnology but, propelled primarily by commercial interests, biotech is proliferating across the globe. Thus, the US posture on research transparency does and will continue to have significant influence on the global regulation of biotechnology and, more generally, the relationships between biological sciences and society. Transparency will help alleviate concerns about abuse of biotechnology, while secrecy will encourage mistrust, possibly prompting a "biodefense race" scarcely removed from an offensive one. IBCs are being handed the job of being the key choke point for review of US dual-use biological weapons research and, thus, their transparency has become an international concern.

II RESULTS SUMMARY



The numbers in this report and the replies reproduced herein speak for themselves. There is a crisis in biological research transparency in the United States. It extends through all sectors – universities, institutes, government, and private companies. Although federal guidelines require institutional biosafety committees (IBCs) to make meeting minutes available to the public upon request, nearly half (45%) of the National Institutes of Health registered IBCs are unwilling to do so or unable to, frequently because the IBC is in a state of disrepair. Among those that did produce meeting minutes, most failed a standardized (and forgiving) transparency evaluation.

Less than 5% of the nation's IBCs are operating with an adequate level of public disclosure. Secrecy in biodefense and biotechnology research extends across the IBC system. The most opaque IBCs are at laboratories operated by the government itself as well as those of biotechnology companies. Even among the better-performing sectors - public universities and non-profit research institutes - disclosure is poor. A third of public universities could not produce IBC meeting minutes, and fully half failed a transparency evaluation.

Some IBCs not only do not disclosure the nature of specific research projects, they try to prevent revealing the existence of high containment laboratory facilities.[6]

Almost three decades have passed since the historic Asilomar conference. At Asilomar, proponents of the then-emerging science of genetic engineering forestalled federal regulation by agreeing to an accountable institutional biosafety committee system under federal "guidelines" – and not law. Thirty years - and many patents - later, the Asilomar commitment has plainly fallen apart.[7] Even the government itself does not follow the guidelines. Three out of five federal labs could not produce minutes of their IBC meetings. The Departments of Energy and Agriculture have splintered off from the National Institutes of Health, master of the IBC system. The Department of Defense is nowhere to be seen in the IBC system.

Scores of biotech companies, including major corporations and three dozen with current "bioterrorism" grants from NIH, do not even have registered IBCs. Less than one in four companies – counting only those that are registered – replied to the survey, despite the Guidelines' requirement to do so.

From an early stage, the National Institutes of Health was made aware of the serious problems (both with transparency and the mere functioning of IBCs) indicated by the response to this survey. Even before the release of this report, NIH took modest steps to try to encourage IBCs to comply with the NIH Guidelines. NIH's Office of Biotechnology Activities (NIH OBA) issued suggestions in the form of "question and answer" and "guidance" documents. These efforts did not work, in large measure because NIH has no legal authority over IBCs. In the end, IBCs comprise a voluntary system that has failed at its present task.

Ominously, the deeply troubled IBC system now must absorb an even greater charge: ensuring security and good judgment in dual-use biodefense research. This mandate, again voluntary, will come from the recently established National Science Advisory Board on Biosecurity (NSABB), which, like the NIH Guidelines, operates under the auspices of NIH OBA.

Nothing short of a dramatic overhaul, including mandatory compliance, detailed disclosure requirements, and international standards for biotechnology laboratory operations, will place the system on a sound footing. Detailed recommendations are presented in Section VIII.

III METHODS AND CONDUCT

In October 2003, the Sunshine Project obtained an electronic spreadsheet with the names, addresses, and contact information of the 439 institutional biosafety committees (IBCs) registered NIH's Office of Biotechnology Activities (NIH OBA), the federal office that oversees IBCs and is in charge of the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines), the blueprint document for the IBC system. NIH OBA provided the spreadsheet under a Freedom of Information Act (FOIA) request.

In January 2004, the Sunshine Project prepared signed letters addressed to the NIH's designated contact for all of the IBCs. Each identical letter requested minutes of the two most recent IBC meetings of the institution. The letter cited the NIH Guidelines at *Section IV-B-2-a-(7)* and provided the relevant text: **"***Upon*

[6] Such as the University of Texas Health Science Center at San Antonio. In its reply to the survey, the University redacted significant information from its IBC minutes, arguing that divulging it posed a security threat. In a procedure under Texas state open records law, the Sunshine Project filed an objection. The state's Attorney General ordered the material released (Open Records Letter Ruling OR2004-7509). The unedited IBC minutes revealed that the University had sought to withhold references to the fact that it is constructing new BSL-3 laboratory facilities.

[7] In 2000, *The Scientist* published a discussion with a 25 year retrospective on Asilomar (14[7]:15, Apr 3 2000), available online at the URL: http://www.the-scientist.com/yr2000/apr/russo_p15_000403.html

request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes..." The letter also asked each IBC to indicate if the institution handled bioweapons agents by circling one option in the following sentence: "[Institution name] *IS / IS NOT registered to handle select agents*."[8]

On 28 January, the process of sending the faxes began. For 98 registered IBCs, NIH OBA had no fax number on file. In addition, approximately 75 numbers indicated in the NIH OBA spreadsheet proved to be incorrect. Using institution websites, personnel directories, and by telephone, fax numbers were identified for as many IBCs as possible. On 31 January, the last of the survey letters was sent. In total, 390 IBCs were surveyed, or 88.8% of those registered.[9] The survey letter requested a reply by 1 March 2004.

Unexpectedly, the survey quickly generated discussions on internet listservers of the American Biological Safety Association (ABSA) and the National Association of College and University Attorneys, whose membership together include biosafety staff and/or legal counsel for the vast majority of IBCs surveyed.[10] Despite the clear language of the NIH Guidelines at IV-B-2-a(7), some institutions decided to refuse to reply[11] while others delayed their answer to observe the response of other IBCs.[12] A group of IBCs replied by saying their IBC minutes were only available to the public by inspection at their offices, often imposing requirements such as several weeks' advance notice, mandatory "supervision", fees, etc.

Although the NIH Guidelines unambiguously required a response, the initial reaction to the survey letter by many IBCs resulted in a poor rate of reply by 1 March 2004.[13] Statistics on survey response were posted online, including an indication that replies were still expected, and reiterating that the NIH Guidelines required it. Surveyed institutions and NIH regularly consulted the statistics. In late March, a response was again requested (by fax, e-mail, and US mail) from dozens of IBCs, an effort that focused on larger institutions that had not replied, particularly those conducting biodefense research. After attempting to resolve the problem directly, on May 3rd, the Sunshine Project filed a complaint with NIH OBA against nine institutions[14] that continued to refuse to make minutes available outside their offices. On May 15th, NIH OBA issued a document, *Questions and Answers Concerning Institutional Biosafety Committee (IBC) Meeting Minutes,*[15] which reiterated that IBCs needed to take minutes and make them available to the public.

In June, July, and August, IBCs that had not replied continued to be contacted, including a dozen repeatedly non-responsive IBCs that were sent requests by certified mail.[16] Some late-replying IBCs only provided

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[8] "Select Agent" is the term used by the Centers for Disease Control to describe the biological toxins and organisms (including parts thereof) classified as biological weapons agents. Institutions that possess select agents (in some cases over a certain amount) must register themselves and their relevant researchers with CDC or USDA.

[9] In addition, one IBC (at a public university) that was not surveyed replied. This is probably because the same university system has two IBCs in the same city, apparently operating with the same biosafety staff.

[10] Personal communications with biosafety officials at institutions with clinical programs also indicate that companies sponsoring biopharmaceutical trials quickly contacted IBCs to guide their response.

[11] Such as the Mt. Sinai School of Medicine in New York City, whose Biosafety Officer wrote to his counterparts, *"Quite frankly...we ignored* [the Sunshine Project]*... we will honor their request when and only when directed by the NIH to do so!!"* Further ignoring the NIH Guidelines, Mt. Sinai declared that access to its IBC minutes *"is on a need to know basis"* (ABSA listserver, 19 and 22 March 2004). Mt. Sinai's bravado was a bluff that unraveled embarrassingly. Mt. Sinai's legal counsel later admitted to NIH OBA and the Sunshine Project that it had no meeting minutes. Mt. Sinai's obfuscations, which were intended to hide its IBC's noncompliance, almost certainly had a negative impact on disclosure by institutions whose committees are in better working order. The Mt. Sinai biosafety officer, who is outspoken and well-known among his counterparts, tried to avert disclosure and bolster his position by railing against transparency, thereby drawing colleagues into his bluff.

[12] For example, before replying, the University of Maryland at Baltimore safety director polled other schools, asking "*A member of our IBC believes that few, if any, academic institutions have responded and sent copies of IBC minutes…. I'd like to have some numbers to support or refute that belief. I'm asking members of this listserv who received a letter… to respond… with a simple "yes" or "no" to the question "Did you send copies of IBC minutes to the Sunshine Group?".* (ABSA listserver, 13 March 2004).

[13] The names of those IBCs that provided their minutes by the requested date are listed in italics in section IX.

[14] These were Iowa State University, Cornell University, Washington University, University of Pittsburgh, Duquesne University, University of Arkansas, Southern Illinois University Medical School, Serono Reproductive Biology Institute, and Vical, Inc.

[15] URL: http://www4.od.nih.gov/oba/IBC/IBC_Minute_Q_A.pdf

[16] In the US, certified mail is a type of mail in which the sender receives written confirmation that the letter was delivered to the addressee.

minutes that post-dated the survey letter. In order to ensure consistency, these IBCs were asked to provide additional minutes of meetings that took place prior to February, 2004.

By September 15th, 276 IBCs had made some response to the survey. Not all respondents provided meeting minutes. In addition, more than a dozen IBCs replied with minutes that solely related to clinical biopharmaceutical experiments and such minutes, because of the limited scope of IBC activity, were not evaluated. Subtracting these and the replies of institutions with no minutes or documents described as minutes; but which were too atypical to evaluate,[17] minutes provided by 199 IBCs (51% of those surveyed, 45.3% of all IBCs registered as of October 2003) were determined to be evaluable.

It should be noted that the number of evaluable minutes, while representing a more than half of surveyed IBCs, was unexpectedly low. This, in turn, resulted in unexpected findings: In their replies, 35 institutions that did not produce minutes revealed a range of problems at their IBCs, including committees that do not meet, do not have meeting minutes, or that refuse to provide their minutes. These IBCs are indicated on page 31. In 18 cases, committees reported themselves as inactive or their minutes revealed that they were newly-formed. These IBCs are listed on page 32.

The NIH Guidelines establish the responsibilities of IBCs; but do not mandate a format for IBC minutes. As a result, minutes vary dramatically from IBC to IBC and, often, by meeting of the same IBC. A rigorous, qualitative evaluation of the minutes was performed by assigning IBCs a score for four major criteria. The criteria and their respective ranges were:

Research Descriptions — *0-35*
How well do the minutes convey the nature of research under review? Do the minutes sufficiently describe the specific research, procedures, organisms and vectors, containment, etc, to disclose a meaningful picture of the activity?

Detail of Minutes — *0-25*
How well do the minutes capture the IBCs discussions, particularly in protocol review? Are the questions, comments, and concerns raised at the meeting, and the suggestions / amendments made (if any) adequately related in the minutes?

Scope of Minutes — *0-25*
Do the IBC's minutes simply reflect new protocol voting and adminstrative matters? Do they show how the IBC is attending to broader responsibilities by, for example, addressing accidents, compliance issues, and exerting oversight of active protocols?

Demeanor — *0-15*
Did the IBC respond thoughtfully and reflect that it values openness by, for example, enclosing a letter offering to answer any questions? Did it respond to questions (if any)? Did it promptly honor the request? Did it respond grudgingly or require multiple requests?

In addition to the four basic criteria above, points were added or subtracted as follows:

- *Are the members of the IBC identified (+5), partially obscured (-5), or completely hidden (-10)?*
- *Did the institution clearly indicate whether or not it handles select agents (+5)?*
- *Have the minutes been delivered without redactions (+5)?*
- *If redacted minutes were provided, are they adequately and specifically explained? Are the redactions made explicitly supported by the NIH Guidelines? If redacted under a state law, is the institution using state law to hold information that is otherwise public under the NIH Guidelines?* [18] *No change, -5 or -10, depending on severity.*[19]

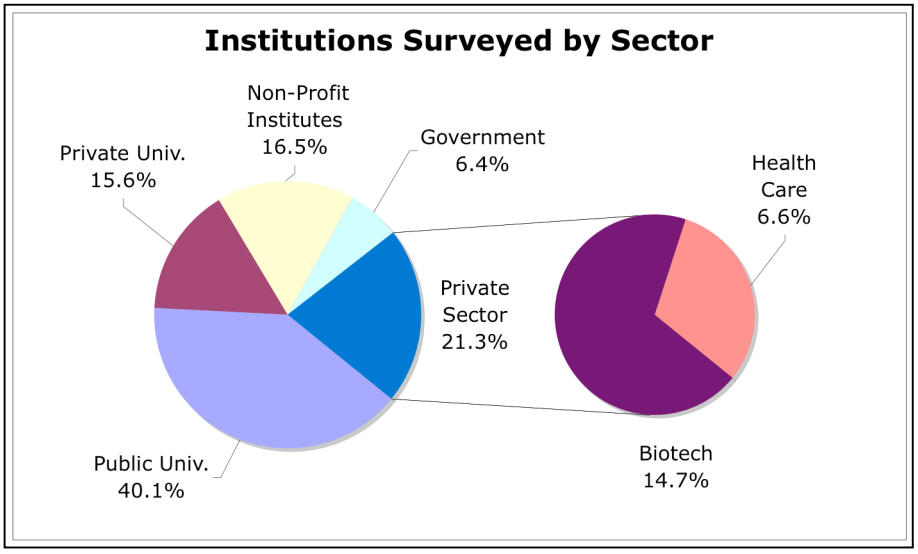
[17] For example, Expressive Constructs, Inc., a Worcester, MA biotech company, replied by sending a laboratory inspection checklist used by a local public health agency, saying that the checklist was its IBC minutes.

[18] For example, two IBCs of the Indiana University system cited a state law and redacted *"information concerning research", "expressions of opinion", "advisory or deliberative material"*, and information *"communicated for the purpose of decision making"*. Not only are these types of redactions not supported by the NIH Guidelines, they defeat the core purposes of the public access provisions, making the minutes unintelligible.

[19] For example, one IBC's minutes contained the name of a patient enrolled in a gene therapy trial, because the patient had experienced a medical problem (called an "adverse event"). The name was redacted to protect the patient's privacy, the IBC explained. Because the removal of

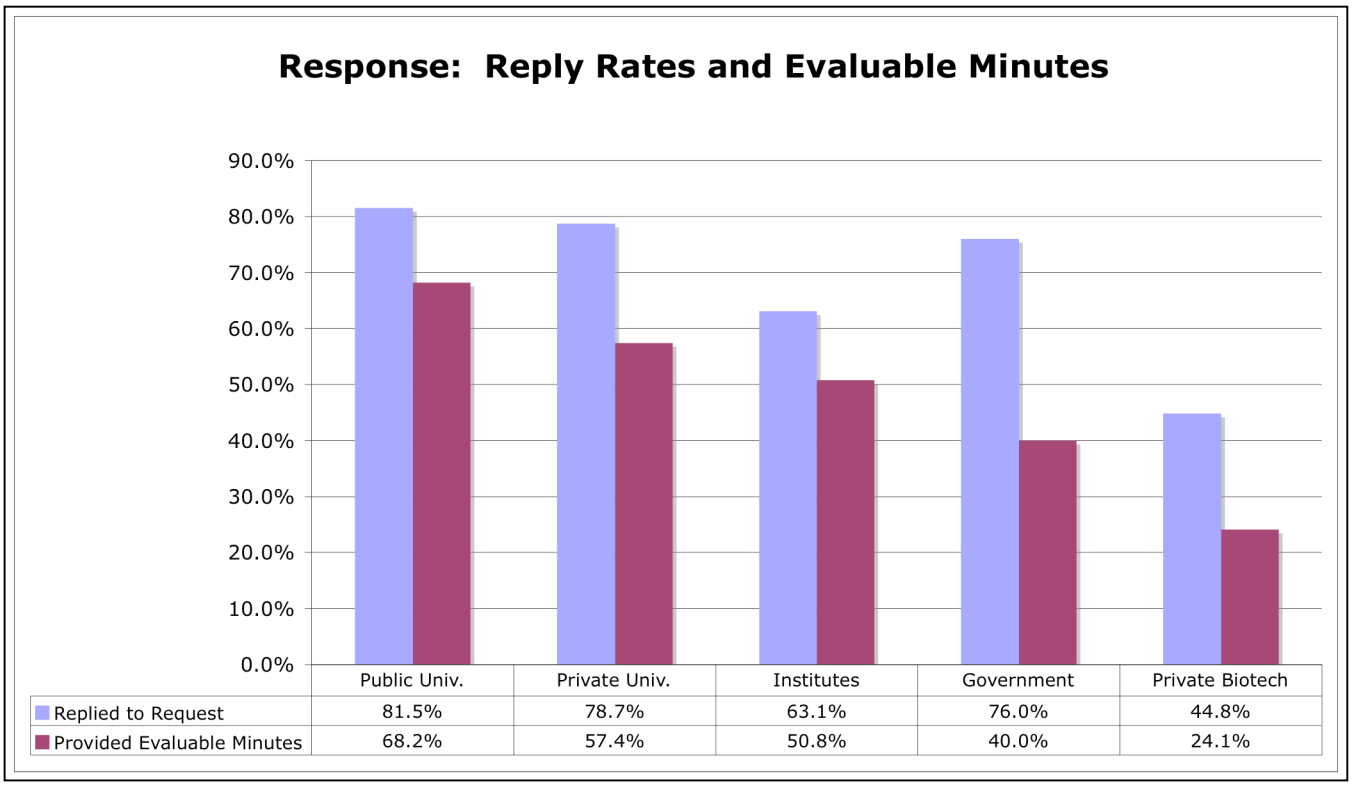
IV RESPONSE RATE

Surveyed IBCs were grouped into five categories: public universities, private universities, non-profit institutes (including non-profit research hospitals), government, and the private sector. The private sector was subdivided into biotechnology companies and health care providers.[20] The proportions of different types of institutions surveyed are illustrated at right.



Response rates, both with and without evaluable minutes, varied markedly by sector. Public universities were most likely to respond, followed closely by private universities and government IBCs. By a wide margin, biotechnology companies were the least likely to respond.

A more telling statistic is that of the IBCs that replied and provided minutes. Here again public universities were most likely to provide minutes (thus meeting the immediate requirement of the NIH Guidelines). Two-thirds did so, a comparatively strong showing. Private schools and non-profit institutes both provided minutes at a more anemic rate, while only two out of every five government IBCs provided minutes. Less than one quarter of biotechnology companies provided meeting minutes. (See illustration below.)



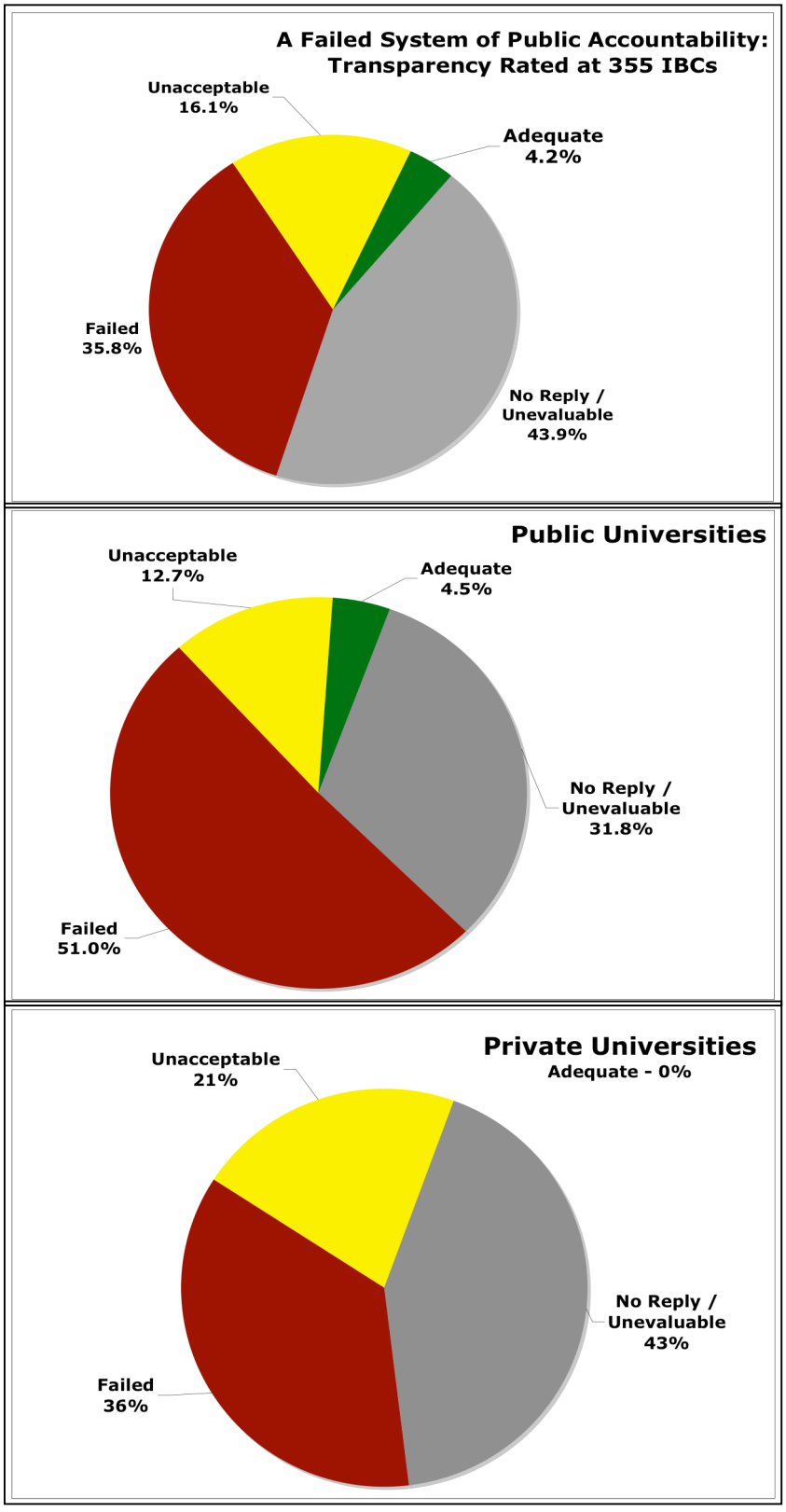
	Public Univ.	Private Univ.	Institutes	Government	Private Biotech
Replied to Request	81.5%	78.7%	63.1%	76.0%	44.8%
Provided Evaluable Minutes	68.2%	57.4%	50.8%	40.0%	24.1%

information was obviously reasonable, the IBC's rating was not reduced. Other institutions, however, redacted their minutes, sometimes heavily, without offering any explanation, much less specific or defensible ones.

[20] These are not counted in statistics for biotechnology companies. See table, page 11.

V TRANSPARENCY RATINGS: OVERALL AND BY SECTOR

Evaluation of the minutes (as previously described) yielded a very unflattering picture of public disclosure by IBCs. Using a forgiving ranking system that granted a bonus for simple compliance (e.g. listing IBC members), and which assessed only minor penalties against IBCs that resisted disclosure,[21] only 15 of the 199 sets of minutes were adequate (≥80 on a 100 point scale). 127 IBCs failed outright (<60), most them severely (≤50). 57 IBCs provided minutes that were somewhat better; but still unacceptable (60-79.9).



Public Universities

The least negative things that can be said about the reply by public university IBCs is that some of them (4.5%) made adequate disclosure. Also, public universities were the most likely to respond at all (81.5%). They were also the most likely provide evaluable minutes - two thirds did so.

Unfortunately, more than half (51%) of all public universities provided minutes rated as failing, and a fifth made no reply at all. Part of the reason why is that, at some universities, serving on the IBC is considered a burdensome and undesirable task. Explaining his committee's poor response, one biosafety officer told the survey "*Many of them* [IBC members] *serve involuntarily. They're appointed, you know*."[22]

Private Universities

Disclosure by private universities is substantially inferior compared to that by state educational institutions. No private

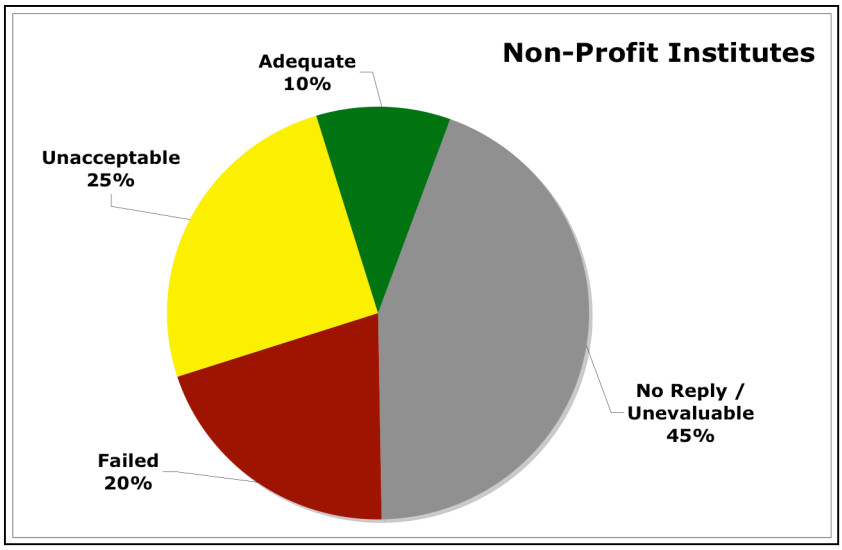
[21] The purpose of the study is to evaluate transparency now and to make recommendations for the future. Accordingly, IBCs that at first resisted disclosure; but subsequently released minutes were not heavily penalized for their former policy. Ironically, several IBCs that fared comparatively well had to be pressured for minutes. One (University of Pittsburgh) did not reply until after a formal complaint to NIH OBA. Another (St. Jude's) replied only after three requests. In both cases, however, the minutes were superior to those of the majority of institutions. IBCs that did not throw up obstacles to public release and quickly answered the survey with minutes are noted in Section IX by appearing in *italics*.

[22] Personal communication, BSO of a public university in the Northeast.

university provided minutes rated as adequate, and 43% failed to provide evaluable minutes at all.

Very modest encouragement might be found in the fact that a fifth (21%) of private universities provided minutes that were not outright failures.

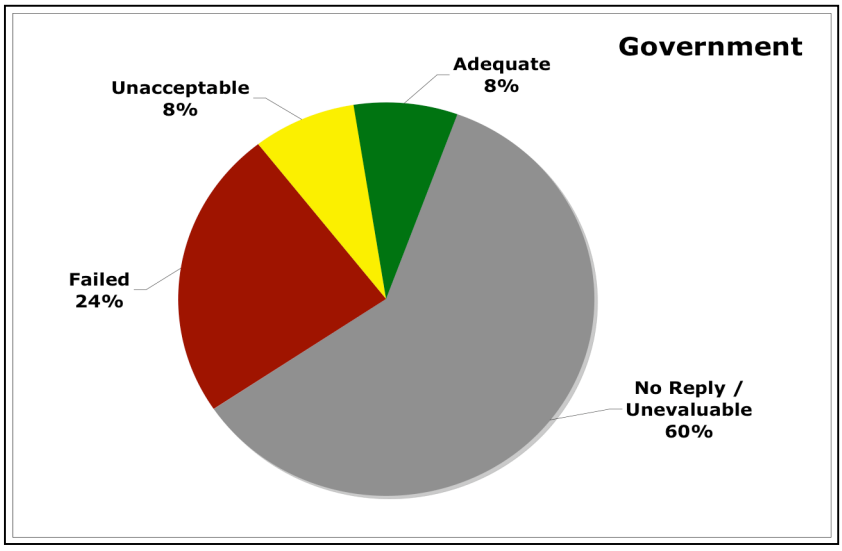
Non-Profit Institutes



The highest percentage of IBCs with adequate disclosure (10%) can be found in the non-profit sector. Despite the relatively high number of adequately performing institutes, a fifth were rated as failures and more than two fifths (45%) did not reply with evaluable minutes.

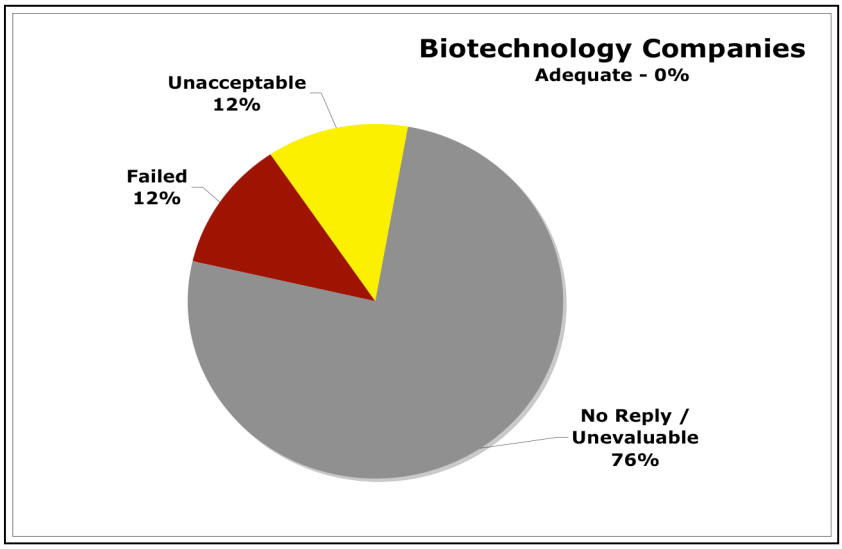
The sharp divides in performance of institutes is in part attributable to the diverse types of institutions in this sector. Adequate performers included non-profit research hospitals and community health systems (including such institutions working with biological weapons agents). Defense science contractors dragged down the sector's overall performance – a finding that has implications for other sectors as the number and types of institutions conducting biodefense research expands.

Government



The public accountability of government IBCs is extremely poor. While two of the 25 government IBCs surveyed provided adequate disclosure, this pair is an exception to the general pattern. Three out of five government IBCs, including USDA, DOE, DOD committees and even an IBC of NIH itself, either did not reply to requests for their minutes or were unable or unwilling to provide minutes. Most of the minutes that were provided were rated as failing. In addition, a notable number of federal laboratories, including the US Army at Ft. Detrick, Maryland, do not maintain NIH-registered IBCs (see Section VII).

The implications of government IBCs' failure to follow the NIH Guidelines are important. Because the Guidelines are run by the federal government; but are not legally binding, in order for them to work in other sectors, it is important for government research to set an example of compliance. Instead, government IBC disclosure is poorer than that of universities and research institutes. This disregard broadcasts a message to other sectors that the Guidelines need not be followed.



Biotechnology Companies

Perhaps taking their cue from federal IBCs, biotechnology companies compose the only sector that underperformed the government's already painfully low mark. Three quarters of biotech company IBCs did not reply to the survey or could not provide evaluable minutes. None of the companies that replied with minutes provided adequate disclosure.

Despite the extremely poor response, all of the biotech companies surveyed maintain NIH-registered IBCs. The fact that three quarters of NIH-registered biotech company IBCs do not comply with the NIH Guidelines itself demonstrates that the private sector does not adhere to lab safety rules that lack legal force. This is only the tip of the problem, however, because there are many biotech companies that refuse to even register an IBC with NIH (*see next section*).

PUBLIC UNIVERSITIES

Number	157
Replied	128 (82%)
Provided Evaluable Minutes*	107 (68%)
Overall average rating (n=157): (Max 86.3, Min 0)	31.9
Average of evaluable minutes	46.8

PRIVATE UNIVERSITIES

Number	61
Replied	48 (79%)
Provided Evaluable Minutes	35 (56%)
Overall average rating (n=61) (Max 77.5, Min 18.75)	28.9
Average of evaluable minutes	50.3

NON-PROFIT INSTITUTES

Number	65
Replied	41 (63%)
Provided evaluable minutes	33 (56%)
Overall average rating (n=59) (Max 90.9, Min 0)	31.9
Average of evaluable minutes	57.1

GOVERNMENT

Number	25#
Replied	19 (76%)
Provided evaluable minutes	10 (40%)
Overall average rating (n=25) (Max 83.1 Min 25)	21.4
Average of evaluable minutes	53.4

PRIVATE SECTOR TYPE 1 BIOTECH

Number	58
Replied	26 (45%)
Provided evaluable minutes	14 (24%)
Average rating (n=53)† (Max 69.4, Min 20.0)	13.7
Average of evaluable minutes	52.0

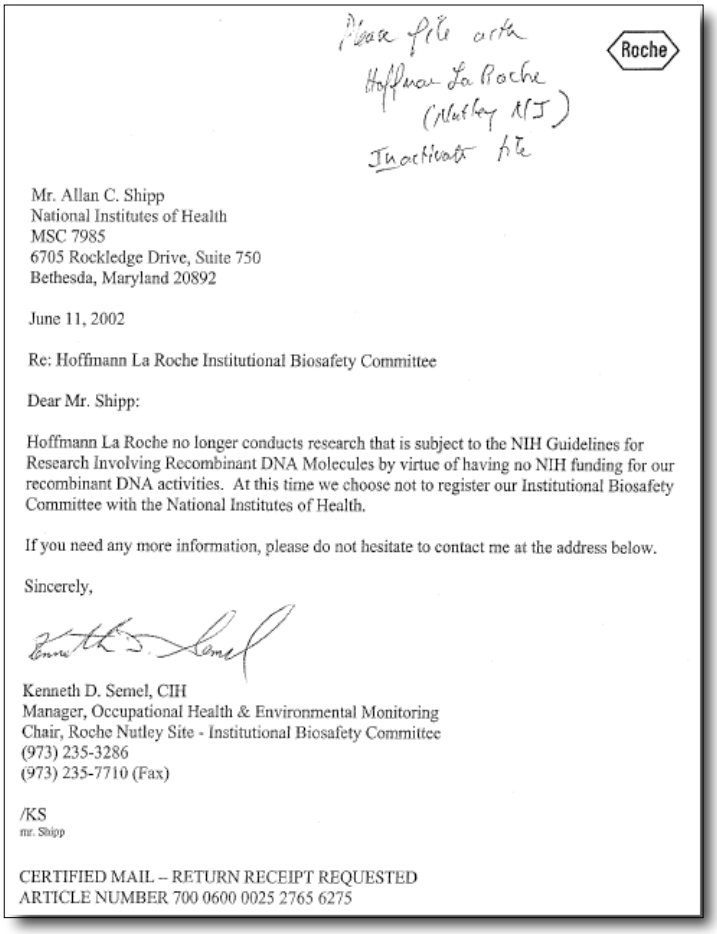
PRIVATE SECTOR TYPE 2: HEALTH CARE

Twenty-six private health providers were surveyed. Of these, 13 responded. Eleven provided minutes indicating that their IBC manages biopharmaceutical trials only and were not evaluated because of the limited scope of the committees' activity. Two reported inactive IBCs. The remaining 13 (50%) did not reply.

* This number excludes IBCs that were insufficiently active or too poorly organized to perform their functions. Excludes IBCs that stated they had no minutes and those that replied; but imposed conditions on access to minutes that do not comport with the requirements of the NIH Guidelines. In the case of institutions, an additional exclusion was made for IBCs whose sole function is to review clinical biopharmaceutical research.

Includes 23 federal IBCs and 2 state IBCs.

† 58 biotech companies were surveyed, including 5 Monsanto Company IBCs (incl. Calgene). After repeated prompting, Monsanto's St. Louis office provided some minutes from some of its IBCs, however, they are not clearly labeled and, in at least one case, are incomplete and post-date the survey request. Because the response was partial and unclear, it was discarded.



Please file with
Hoffman La Roche
(Nutley NJ)
Inactivate file

Roche

Mr. Allan C. Shipp
National Institutes of Health
MSC 7985
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

June 11, 2002

Re: Hoffmann La Roche Institutional Biosafety Committee

Dear Mr. Shipp:

Hoffmann La Roche no longer conducts research that is subject to the NIH Guidelines for Research Involving Recombinant DNA Molecules by virtue of having no NIH funding for our recombinant DNA activities. At this time we choose not to register our Institutional Biosafety Committee with the National Institutes of Health.

If you need any more information, please do not hesitate to contact me at the address below.

Sincerely,

Kenneth D. Semel, CIH
Manager, Occupational Health & Environmental Monitoring
Chair, Roche Nutley Site - Institutional Biosafety Committee
(973) 235-3286
(973) 235-7710 (Fax)

/KS
mr. Shipp

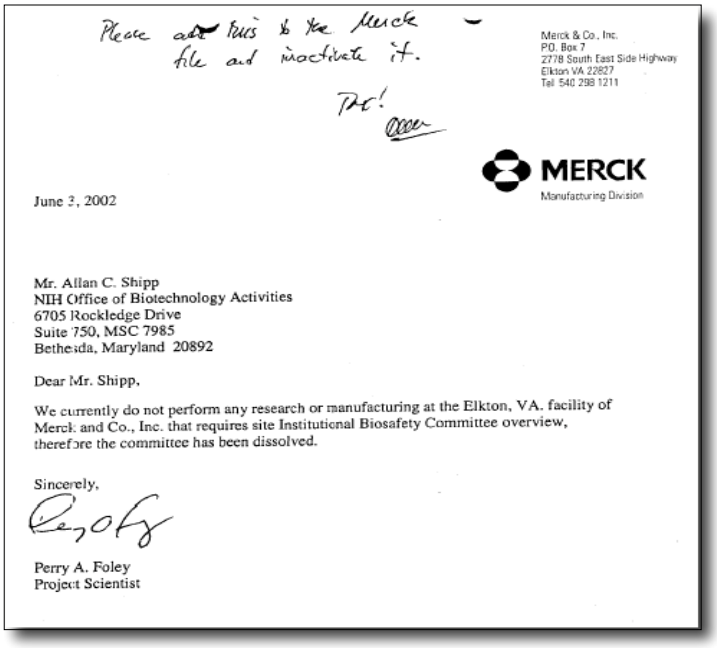
CERTIFIED MAIL – RETURN RECEIPT REQUESTED
ARTICLE NUMBER 700 0600 0025 2765 6275

VI TRANSPARENCY AND OVERSIGHT OF BIOTECHNOLOGY COMPANIES

For any biological research safety and security standards to be effective they must be applied equally. Without the frequently invoked "level playing field", disincentives to compliance and, by direct implication, dangerous situations emerge. After all, IBCs exist to address universally-acknowledged risks associated with biotechnology research and the IBC system is now being given the additional charge of ensuring safety, security, and good judgment in dual-use biodefense research.

If a small proportion of institutions don't play by the rules, much less a large one, the integrity of the system cannot be ensured. Immediately there is the problem of non-compliant research and the long-term trend would be for riskier or otherwise unconductable experiments to gravitate toward noncompliant institutions.

In this sense, this survey's finding that less than 25% of registered biotechnology companies IBCs comply with the NIH Guidelines' public access provisions is problematic enough in itself. In addition, those comparatively few replies received reveal problems in the composition and operation of private sector IBCs. For example, some private sector IBCs do not review specific research projects and instead issue blanket approvals, for example, giving a green light to (all) "research at BSL-2" at a company – without regard to the specifics of projects.



Please add this to the Merck
file and inactivate it.
Thx!

Merck & Co., Inc.
P.O. Box 7
2778 South East Side Highway
Elkton VA 22827
Tel 540 298 1211

MERCK
Manufacturing Division

June 2, 2002

Mr. Allan C. Shipp
NIH Office of Biotechnology Activities
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, Maryland 20892

Dear Mr. Shipp,

We currently do not perform any research or manufacturing at the Elkton, VA. facility of Merck and Co., Inc. that requires site Institutional Biosafety Committee overview, therefore the committee has been dissolved.

Sincerely,

Perry A. Foley
Project Scientist

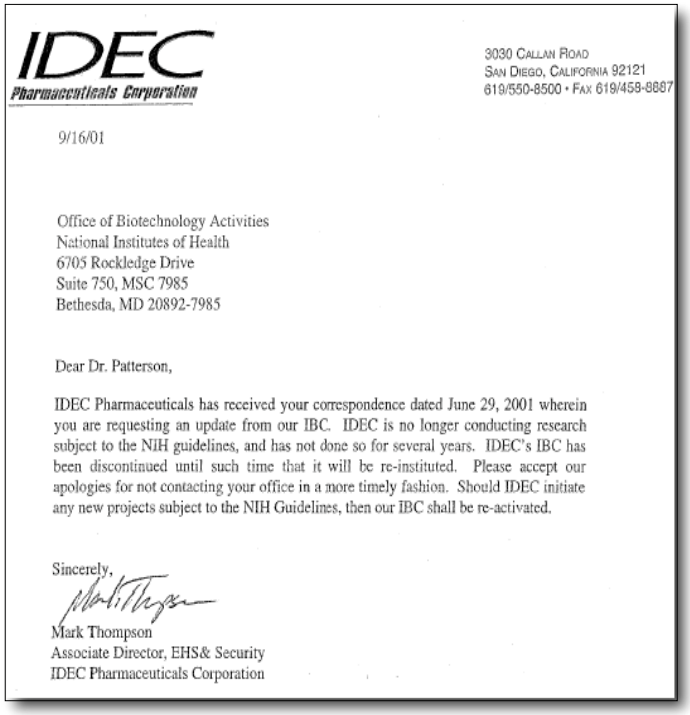
Even more importantly, however, a cursory examination of NIH OBA's registry of IBCs immediately reveals a huge problem. Hundreds of biotech companies, ranging from global conglomerates (such as Roche, see above) to boutique operations do not appear on the list.[23] In addition, if registered at all, companies frequently have IBCs at only some of their research and production sites (such as Merck, see right). One company notable for being not registered at all is

[23] The problem, while rampant in the private sector, is not unique to it. For example, neither the Lovelace Respiratory Research Institute nor the Midwest Research Institute (MRI) has a registered IBC. Both of these institutes have DOD biodefense contracts, large aerosol chambers, and BSL-3 facilities including, in MRI's case, biological labs in at least three states – Missouri, Florida, and Maryland.

California-based Allergan, which manufactures the biological weapons agent botulinum toxin (marketed as BoTox).

It was beyond the scope of this survey to fully quantify the number of biotechnology companies that do not adhere to the NIH Guidelines, however, it did attempt to ascertain the scope of private sector noncompliance and the relevant relationships between NIH OBA and biotech companies. To do this, NIH research grants were reviewed to determine if private sector recipients had registered IBCs, a test of both the private sector's commitment to the Guidelines and NIH's commitment to its policy of requiring compliance with the Guidelines by its grantees.

Also, the survey hypothesized that the strengthened role for IBCs in review of dual-use research, first discussed by the National Academies and then via the establishment of the National Science Advisory Board on Biodefense (NSABB), would cause disquiet in the private sector, possibly leading companies to further distance themselves from the NIH Guidelines. To test this proposition, a Freedom of Information Act request was filed for letters from institutions asking to be removed from the NIH registry, termed "inactivation requests" by NIH OBA.



IDEC
Pharmaceuticals Corporation

3030 Callan Road
San Diego, California 92121
619/550-8500 • Fax 619/458-8867

9/16/01

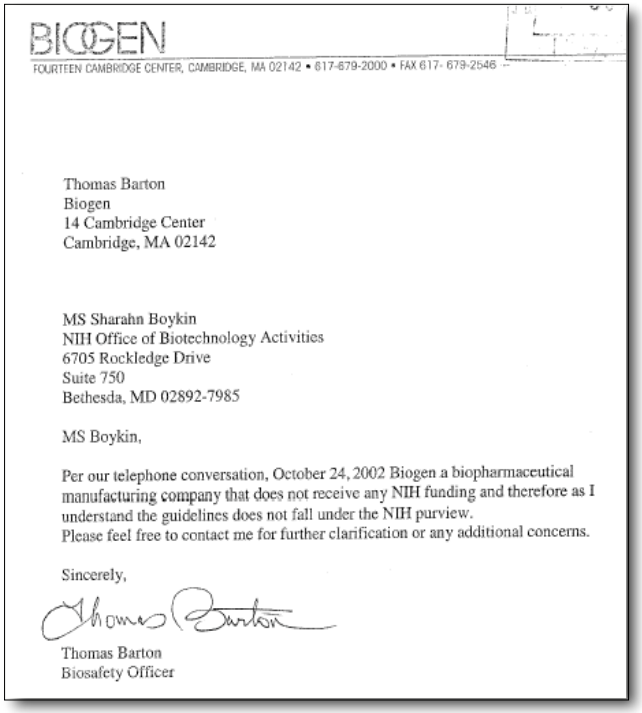
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Dr. Patterson,

IDEC Pharmaceuticals has received your correspondence dated June 29, 2001 wherein you are requesting an update from our IBC. IDEC is no longer conducting research subject to the NIH guidelines, and has not done so for several years. IDEC's IBC has been discontinued until such time that it will be re-instituted. Please accept our apologies for not contacting your office in a more timely fashion. Should IDEC initiate any new projects subject to the NIH Guidelines, then our IBC shall be re-activated.

Sincerely,

Mark Thompson
Associate Director, EHS& Security
IDEC Pharmaceuticals Corporation



BIOGEN
FOURTEEN CAMBRIDGE CENTER, CAMBRIDGE, MA 02142 • 617-679-2000 • FAX 617- 679-2546

Thomas Barton
Biogen
14 Cambridge Center
Cambridge, MA 02142

MS Sharahn Boykin
NIH Office of Biotechnology Activities
6705 Rockledge Drive
Suite 750
Bethesda, MD 02892-7985

MS Boykin,

Per our telephone conversation, October 24, 2002 Biogen a biopharmaceutical manufacturing company that does not receive any NIH funding and therefore as I understand the guidelines does not fall under the NIH purview.
Please feel free to contact me for further clarification or any additional concerns.

Sincerely,

Thomas Barton
Biosafety Officer

NIH OBA provided 33 deregistration letters, 19 of which came from biotech companies.[24] Due to mergers and other company changes, however, it is unclear exactly how many operating biotech facilities that were at one time registered have recently opted out of the NIH Guidelines. Nevertheless, some of the "inactivation letters", reproduced on this and the previous page, make clear that many biotechnology companies, including the largest, are unwilling to adhere to the NIH Guidelines.[25]

Turning to NIH grants, searches were performed in NIH's award database for private companies receiving NIH funding for research whose abstract suggests that it involves recombinant DNA.[26] The search was restricted to a particularly relevant type of grant, those matching the keyword

[24] Of the remainder, seven came from non-profit institutes (including Battelle Memorial Institute, a biodefense contractor), five from private universities, one from a public university, and one from the US Army RDECOM (formerly SBCCOM) at Ft. Natick, MA.
[25] IDEC and Biogen, both biopharmaceutical companies, merged in November 2003.
[26] CRISP, NIH's online grants database, may be accessed at the URL: http://crisp.cit.nih.gov/

"bioterrorism". The searches identified 37 private biotech companies that do not have a registered IBC; but have recently received bioterrorism-related funding from NIH.[27] The implications of this situation are: 1) NIH is not following its own policy in grantmaking – it is awarding biodefense grants to institutions that do not follow the NIH Guidelines; 2) noncompliance is deeply ingrained in the private sector – many biotechnology companies plainly do not feel the need to register IBCs before seeking biodefense funding; and 3) lax enforcement of NIH policy by NIH OBA and the National Institute of Allergy and Infectious Disease (NIAID), the awarding agency in most cases.

Some Private Companies with NIH Funding and No NIH-Registered Biosafety Committee

The following companies received one or more NIH grants from 2001 through 2004 (to June 30th) that both (a) match the keyword "bioterrorism" and (b) appear, on the basis of the public abstract, to involve recombinant DNA and, thus, require that the company maintain an NIH-registered (and, obviously, compliant) IBC. Please note that this list only includes companies receiving grants meeting both criteria. A list of all companies receiving all NIH grants for work that involves rDNA – i.e. not simply grants matching the keyword bioterrorism – would be much larger. As of March 2004, none of these institutions had an IBC registered with NIH.

Apovia
San Diego, CA
Avanir Pharmaceuticals
San Diego, CA
BCR Diagnostics
Jamestown, RI
Biodefense Tech., Inc.
Blacksburg, VA
Biolink Partners
Watertown, MA
Biological Mimetics
Frederick, MD
Biopeptides, Inc
Stony Brook, NY
Biorexis
King of Prussia, PA
Cangene Corp.
Mississauga, ON, Canada
Cellex, Inc.
Gaithersburg, MD
Coley Pharmaceutical
Wellesley, MA
Creatv Microtech, Inc.
Potomac, MD
Diversa Inc.
San Diego, CA
Dynavax, Inc.
Berkeley, CA
Echelon Biosciences
Salt Lake City, UT
Elitra Pharmaceuticals
San Diego, CA
Ematagen, Inc
Madison, WI
Epoch Biosciences
Bothell, WA
Genebact Technologies
Marietta, OH
GenPhar
Mt. Pleasant, SC
GLSynthesis, Inc
Worcester, MA
Hematech, LLC
Westport, CT
ioGenetics
Madison, WI
Modular Genetics
Woburn, MA
Molecular Express
Los Angeles, CA
Mpex Pharmaceuticals
San Diego, CA
Nomadics, Inc
Stillwater, OK
Operational Tech.
San Antonio, TX
Planet Biotechnology
Hayward, CA
Radiation Monitoring Dev.
Watertown, MA
RxKinetix, Inc.
Louisville, CO
Sequoia Pharmaceuticals
Gaithersburg, MD
SeqWright, LLC
Houston, TX
Siga Technologies
New York, NY
Therapeutic Systems Res
Ann Arbor, MI
Vaccinex, Inc.
Rochester, NY
VirRx, Inc
St. Louis, MO

The 24.1% biotech company response includes committees whose composition does not comport with the Guidelines and/or whose minutes and (lack of) activities strongly suggest that they are *pro forma* IBCs that do not fulfill their responsibilities. In a limited search, we have identified 37 companies that appear to be required to have registered IBCs; but do not. In addition, there are hundreds more private sector facilities conducting biotechnology research, not presently receiving NIH funding, and which are not registered. Based on the above, it would be a generous to conclude that 10% of biotech companies operate in compliance with the NIH Guidelines.

Accordingly, the study finds that biotechnology companies, as a sector, do not comply with the NIH Guidelines and that any claim to the contrary is not credible. The study also finds that the government is not making any significant effort to achieve the sector's compliance. (See box on USDA, below.)[28]

[27] This number excludes companies such as DOR Biopharma (Miami, FL) which has no registered IBC and receives rDNA funding; but appears to contract all research out to institutions that have registered IBCs where, presumably, it is reviewed. In DOR Biopharma's case, Thomas Jefferson Univ. (Philadelphia, PA), Univ. of Texas Southwestern (Dallas), and Southern Research Institute (Birmingham, AL) all conduct research projects funded by NIH via DOR. None of these institutions themselves fared well in the survey, particularly the latter two, which were rated among the poorest. It is possible that some of the 37 companies have arrangements similar to DOR Biopharma's, although this was impossible to determine from NIH's database and the company websites (when available).

[28] These findings should be noted by regulators in all countries, particularly those in the process of developing national biosafety legislation, some of whom may be incorrectly informed by representatives of the US government and/or biotechnology industry.

Community IBC Members: A Question of Qualifications or a Case of Inbreeding?

A touchy subject among IBCs is the NIH Guidelines requirement for so-called community members. A large number of IBCs ignore the rule to have two such members. More adopt questionable practices to satisfy the requirement. The term "community member" is something of a misnomer. What the Guidelines require are members who are not affiliated and who represent community interests, which are very loosely identified:

> **Section IV-B-2-a-(1).** … At least two members shall not be affiliated with the institution … and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community).

In practice this provision of the Guidelines, if it is followed at all, is typically interpreted to mean local health officials, former or retired employees, or people from surrounding medical or research institutions, such as local universities, hospitals, and in more than one case, military bases. Frequently, the "community member" of one IBC is a biosafety professional who works for an IBC at another local institution. The loose language of the Guidelines encompasses far more potential types of "community members", including local environmental groups and/or watchdogs, however, no case of an IBC recruiting or appointing a representative of a watchdog organization or a community environmental non-profit was identified in this survey. (Although this is inconclusive, because minutes frequently do not state the affiliations of IBC members.)

Some of the "community members" on IBCs who have close relationships with the institution take their community interest responsibilities seriously. Institutions claim that recruiting members with biosafety committee experience, even if they come from very close quarters, improves the functioning and expertise of their IBCs. Some IBCs recruit students, which arguably gives future scientists a valuable introduction to biosafety; but it is unlikely that a student would effectively represent community interests on a committee composed of faculty.

The numerous instances the survey identified of IBC inbreeding, however, strongly suggest that the priority of many institutions in selecting community members are clubbish – intended to minimize the potential for upset to the research approval process and, sometimes, to use IBC community member slots as a way to reinforce links between members of the close-knit community of biosafety professionals. For example:

- The Sandia National Lab IBC (based in Livermore, CA), recruited a just-retired Assistant Director of Lawrence Livermore National Lab as a community member.
- Lawrence Berkeley National Lab, in nearby Berkeley, CA, does not list its IBC members' affiliations, however, its roster includes a biosafety officer at Livermore Lab, presumably as a community member.
- In New Mexico, the Los Alamos National Lab IBC lists a member who is (surprise!) a biosafety officer at Livermore Lab, again presumably as a community member.
- Livermore Lab, in turn, refuses to divulge the names of its community members.
- At the University of California at Davis, the "unaffiliated" IBC members are a biosafety officer from the University of California at Berkeley and an employee of the (local) Chiron Corporation (which itself did not reply to the survey).

California is not the only place where such intricate relationships frequently occur:

- Georgia State University (GSU) recently proffered a *quid pro quo* with Georgia Tech, another Atlanta school. According to Georgia Tech's IBC minutes, a GSU IBC member "*offered to join* [the IBC] *as a community member in return for having a Georgia Tech member serve on the GSU* [committee]."
- At the University of Washington (UW), a community seat is held by an employee of Zymogenetics, a local company founded by UW professors. When the IBC discussed primate research that some might find objectionable, the member expressed concern about what would happen when the community found out. Was this a representation of community interests or a warning to hide from them? The answer isn't at all clear. There was no recorded discussion of the issue and the research was approved.

USDA Biotechnology Grants and the NIH Guidelines

NIH's inattention to compliance with its own Guidelines is mirrored at the US Department of Agriculture (USDA). According to USDA regulations (7 CFR 3015.205(b)3), biotechnology research that it supports must comply with the NIH Guidelines; but this rule is typically ignored.

Formerly, all recipients of USDA biotechnology research grants were required to sign and submit a document called a Research Assurance Statement, wherein they certified that they would comply with the NIH Guidelines. In February 2001, however, USDA's Agricultural Research Service (ARS) stopped asking grantees to make this certification.

The survey requested ARS' policy memoranda and the paper trail related to this decision. Under FOIA, ARS replied that it has no responsive records, suggesting that ARS deliberately left no record of the decision or that it held the NIH Guidelines in such low esteem that it whimsically dispensed with them.

While other USDA grantmaking agencies continue to use a research assurance statement, and USDA's sloppily-written regulation requiring IBCs remains on the books, in reply to a FOIA request, USDA estimated that it has statements certifying compliance on file for only 50% of relevant grants.

USDA has thus abandoned serious attempts to ensure compliance with the NIH Guidelines.

VII TRANSPARENCY AND OVERSIGHT AT GOVERNMENT LABORATORIES

An important reason why the performance of government laboratories in this survey was very poor is the fractured oversight of federal biotechnology and biodefense research. Each major agency has its own rulebook, some of which require compliance with the NIH Guidelines and some of which do not. The rulebooks might or might not be followed by the agency's labs. Sometimes, marked differences are apparent even within agencies. This extends to the Department of Health and Human Services (NIH's parent) itself - the Centers for Disease Control's National Center for Infectious Disease, which operates a BSL-4 laboratory, did not reply to this survey.

The Department of Energy, which operates many biotechnology labs, some of which have significant biodefense programs, has a rule[29] requiring Guidelines-compliant IBCs at its facilities. But the existence of this rule does not mean that DOE facilities actually follow it and, in fact, many labs don't. Argonne National Laboratory near Chicago, home of a NIAID-funded Regional Biocontainment Laboratory, does not have an NIH-registered IBC. Pacific Northwest National Laboratory (Richland, WA), which has conducted biotechnology research for years, including at BSL-3, did not register its IBC with NIH OBA (or, perhaps, did not have an IBC) until this year.[30]

Even among DOE labs that are NIH-registered, there is confusion about the applicability of the NIH Guidelines. In fact, NIH OBA itself appears to be unsure who, exactly, is responsible for DOE IBCs, confusion that stems in part from the fact that many DOE facilities are government-owned; but operated under contract by universities, private companies, and research institutes.

The National Renewable Energy Laboratory (NREL, located in Golden, CO) is a DOE facility with an NIH-registered IBC. NREL refuses to make its minutes available to the public. Operated by Battelle Memorial Institute and Midwest Research Institute, NREL replied to the survey by asserting that it "*voluntarily follows the Guidelines as an industry best-practice in the management of our laboratory activities involving recombinant DNA research*" and that, hence, NREL is free to pick and choose which parts of the NIH Guidelines it wishes to follow, and that the public access provisions aren't parts

[29] DOE N 450.7

[30] As a result, PNNL was not included in this survey.

that it chooses to observe.[31] Note that NREL not only does not follow the Guidelines, it has demoted them to "best-practice" status.

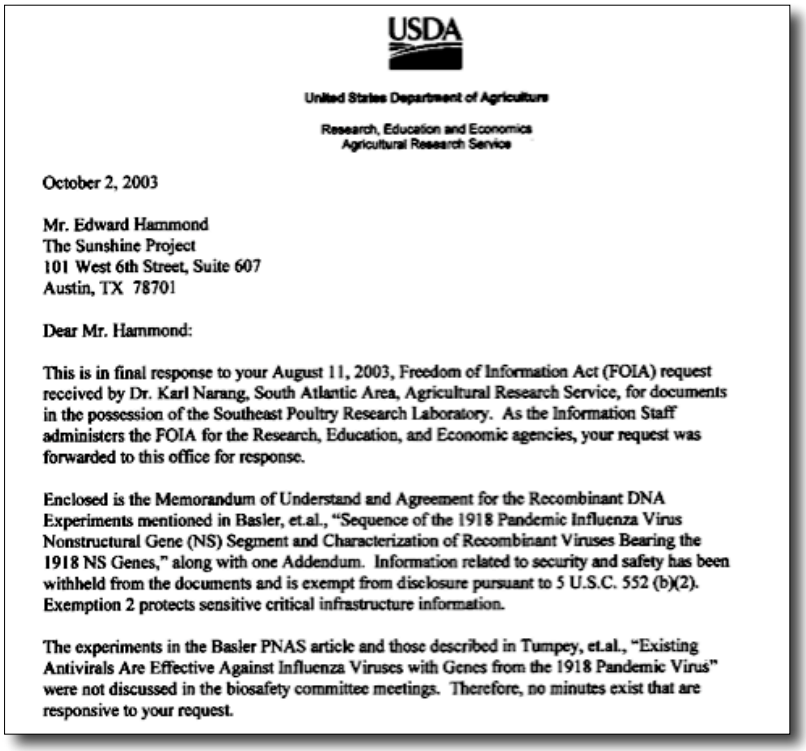
The confusion doesn't stop there. The IBC of the Idaho National Engineering Laboratory (INEL, located in Idaho Falls) has only met once in its history. At the November 2002 meeting, INEL's committee discussed the basics of what an IBC is. It did not review research at the lab and it did not subsequently meet. Despite a contrary requirement in the NIH Guidelines, Brookhaven National Lab (Upton, NY), replied to the survey by selectively deleting information on some of the projects its IBC has reviewed, saying that only part of the research at the lab is subject to the Guidelines.

Sandia National Lab's IBC is another curious affair. Sandia provided the minutes of a single IBC meeting which, like INEL's, are the only meeting it has ever held. The minutes suggest that rDNA work is taking place outside of the IBC's purview. The minutes of the committee's review of a project involving production of a large amount of transgenic microorganisms read:

> *H*[redacted]-*3*
> *Production of over 10L of stuff.*
> *Concern control of quantity and destruction of the solution*.

A committee member then suggests that where this large amount of "stuff" goes should be recorded in a logbook. What the "stuff" is and how and why it is being produced is not stated.

Back at NIH, OBA is unable to clearly identify lines of responsibility for DOE IBCs. Oak Ridge National Laboratory (ORNL) is a DOE facility operated by Battelle Memorial Institute and the University of Tennessee. ORNL's initial response to the survey (which did not provide minutes) was unclear and raised the issue of who was in charge – the contractor(s), the government, or both? When asked directly, NIH OBA deflected the question back to ORNL. Because NIH OBA logically should have a clear idea of who is responsible for registered IBCs, it was asked again. It replied that Oak Ridge National Laboratory is the institution that is responsible, without further (relevant) elaboration. A request for clarification asked to what extent each of the main players at Oak Ridge (DOE, Battelle, and the University of Tennessee) bore responsibility for IBC compliance. Apparently unsure itself, NIH OBA did not reply.



USDA

United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

October 2, 2003

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

Dear Mr. Hammond:

This is in final response to your August 11, 2003, Freedom of Information Act (FOIA) request received by Dr. Karl Narang, South Atlantic Area, Agricultural Research Service, for documents in the possession of the Southeast Poultry Research Laboratory. As the Information Staff administers the FOIA for the Research, Education, and Economic agencies, your request was forwarded to this office for response.

Enclosed is the Memorandum of Understand and Agreement for the Recombinant DNA Experiments mentioned in Basler, et.al., "Sequence of the 1918 Pandemic Influenza Virus Nonstructural Gene (NS) Segment and Characterization of Recombinant Viruses Bearing the 1918 NS Genes," along with one Addendum. Information related to security and safety has been withheld from the documents and is exempt from disclosure pursuant to 5 U.S.C. 552 (b)(2). Exemption 2 protects sensitive critical infrastructure information.

The experiments in the Basler PNAS article and those described in Tumpey, et.al., "Existing Antivirals Are Effective Against Influenza Viruses with Genes from the 1918 Pandemic Virus" were not discussed in the biosafety committee meetings. Therefore, no minutes exist that are responsive to your request.

The US Department of Agriculture (USDA) is another federal agency at which confusion over the applicability of the NIH Guidelines reigns. USDA has several NIH-registered IBCs, none of which produced minutes of an IBC meeting in response to this survey. The majority of USDA's NIH-registered IBCs simply did not have any minutes.
The USDA BSL-3ag[32] labs at the Southeast Poultry Research Laboratory (SEPRL,

[31] Letter from RJ McConnell, NREL, dated 19 February 2004.

located in Athens, GA) take a different approach. They do not have their own IBC and instead rely upon on the University of Georgia's committee, although that IBC cannot be described as functional and compliant with the NIH Guidelines (see illustration, previous page). This is particularly unsettling because SEPRL handles (human) pandemic and highly pathogenic avian influenza viruses, conducting experiments on them without proper review.

Still other USDA labs, including its major research facilities in Beltsville, Maryland, do not have an NIH-registered IBC. USDA researchers at Plum Island, New York now work under an IBC that belongs to the Department of Homeland Security, which replied to the survey by stating that its IBC has not met since DHS assumed control of Plum Island more than a year ago. Finally, as discussed in the box above, USDA does not make an effort to ensure compliance with the NIH Guidelines by its grantees.

If the Departments of Energy and Agriculture (and perhaps even the Centers for Disease Control) can be described as splinter factions from NIH's Guidelines, then **the Department of Defense**, like biotech companies, is a party unto itself. DOD operates its own laboratory safety regime with little to no firm connections to NIH OBA. Most DOD facilities, including labs such as USAMRIID (MD), Aberdeen Proving Ground (MD), Dugway Proving Ground (UT), and others do not have registered IBCs. The same holds true for Navy and Air Force biotechnology labs, such as Navy labs in San Diego, CA, the Naval Research Lab in Washington, DC, as well as a number of Navy labs abroad. Air Force biomedical and research facilities, such as those in and around San Antonio, TX, are also unregistered.

In May 2002, a rare Army lab with a registered IBC (at Ft. Natick, MA) reported to NIH that its committee had been terminated.[33] (Natick continues to conduct biotechnology research. It terminated its IBC because it decided to interpret the NIH Guidelines as not applying to it. NIH OBA dutifully deactivated the committee.)

> -----Original Message-----
> From: Muller, Wayne SBCCOM(N)
> Sent: Friday, May 24, 2002 8:00 AM
> To: 'shippa@od.nih.gov'
> Subject: Termination of IBC
>
> Mr. Alan Shipp
> NIH Office of Biotechnology Activities
> MSC 7985
> 6705 Rockledge Drive, Suite 750
> Bethesda, MD 20892
> (301) 435-2152
>
> Hi Alan,
>
> This email note, per your request, confirms that our Institute
> Biotechnology Committee (IBC) has been officially disbanded. We have
> disbanded the committee because we no longer conduct research subject to
> the NIH Guidelines. If there is any other information needed please let
> me know.
>
> Wayne S. Muller
> US Army, Soldier & Biological Chemical Command
> AMSSB-RSS-MS(N)
> Kansas Street
> Natick, MA 01760-5020
> (508) 233-4596
> fax: (508) 233-5521
>
>

Only a handful of DOD labs are registered under the NIH Guidelines. Of these, only one - the US Military HIV Research Program - produced evaluable IBC minutes.[34] This does not mean, however, that DOD labs do not receive NIH money. The survey identified at least one BSL-4 project, funded by NIAID, with research taking place at USAMRIID.[35] It is likely that there are more. These projects are in violation of NIH policy, which require all NIH-funded biotechnology research to take place in compliance with the NIH Guidelines.[36]

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[32] BSL-3ag is a USDA biosafety standard for labs working with large animals and very dangerous organisms, such as highly pathogenic avian influenza. It is only surpassed by BSL-4, the highest containment level.
[33] E-mail from Wayne Muller, US Army SBCCOM (now RDECOM), Ft. Natick to Allan Shipp, NIH OBA, 24 May 2002. (Received from OBA in FOIA request 30224, reply date 31 August 2004).
[34] Walter Reed Army Medical Center provided IBC minutes which, curiously, pertained only to clinical trials.
[35] Ebola Virus VP40-Host Interactions In Vivo, NIAID grant 1R21AI059277-01.
[36] NIAID is also funding rDNA research at Japanese and Canadian BSL-4 facilities, and in France, none of which is taking place at labs with registered IBCs. These projects were inadvertently discovered by the survey. Detailed research would likely yield many more.

By chance, the survey identified one serious problem in the Army's internal biosafety program. At Oak Ridge National Lab (TN), the Army financed installation of a modular BSL-3 facility, which it undertook to inspect annually. The inspections were not performed for several years, although Oak Ridge's IBC expressed confidence in the non-existent inspections' results.[37]

The Department of Defense's research review system, however, lacks an equivalent to the NIH Guidelines' public access provisions. Thus this survey did not yield copious information about its functioning. The survey does, however, clarify that the Department of Defense does not comply with the NIH Guidelines.

In view of the fact that it is the NIH Guidelines that establish and manage the IBC system and that National Science Advisory Board on Biosecurity (NSABB) will address review of dual-use research through the IBC system, it may be concluded that there is a serious flaw in NSABB's structure. Because DOD effectively does not participate in the IBC system, NSABB's advice and recommendations will be largely inapplicable to DOD labs.

---

[37] See Biosafety Bites #1 for more information.

Out of their League?

In a remarkable moment of candor, at an April 2004 biosafety meeting convened by the White House Office of Science and Technology Policy, a University of Pennsylvania biosafety officer who was particularly concerned about safety in research on bioweapons agents rose to say "*What I want to know is who is going to tell them* [inexperienced scientists] *that they're out of their league?"* (i.e. that a wave of persons with inappropriate training and experience were stepping into dangerous work with bioweapons agents). The government's surprising reply, provided by a consultant from the Massachusetts Institute of Technology, was that research has always followed the money. Because large numbers of scientists could be expected to enter bioweapons research because there are billions of newly-available dollars, the consultant reasoned, the biosafety officer really should not be particularly concerned - it was a typical, deliberately-created state of affairs.

It is generally acknowledged, most often indirectly, that too many scientists with too little training are handling agents that are too dangerous for their experience. The situation has a parallel – seldom acknowledged at all – among the money handlers at the National Institute of Allergy and Infectious Disease (NIAID), who may know their bugs but whose grants suggest they have questionable judgment when it comes to the security implications of dual-use research. That is, NIAID seems a bit out of its league too, when it comes to understanding the (geo)political context of its programs. The following selection of politically-tinged quotes from grants that NIAID has funded since 2002 give pause to consider if NIAID and its biodefense grant recipients adequately understand the political context of biological weapons research:

"*The recent anthrax attack of 2001 underscored the reality of large-scale aerosol bioweapons attack by terrorist groups*"

- Sequoia Pharmaceuticals (NIAID Grant 1R43AI055120-01, 2003).

In fact, there has never been a large scale aerosol bioweapons attack by a terrorist group. Nor is it clear that the 2001 letters were sent by a "terrorist group". Nor has there been any documented use of bioweapons that might reasonably be termed large scale since Japanese use in China during the Second World War. The only known programs that have developed the capacity for a large scale attacks with aerosols have been those of governments, notably the US, USSR, and UK.

"The use of anthrax as an agent of bioterrorism on civilian populations was a theoretical risk, heightened by the discovery that certain rogue nations (notably Iraq, Syria, and China) either had developed or were attempting to develop anthrax or other biologic agents as a weapon of mass destruction"

- Tulane University (NIAID Grant 1R21AI055013-01, 2003)

Iraq almost certainly abandoned efforts to develop bioweapons before the second Gulf War. Syria remains subject to finger-pointing; but some allegations are plainly spurious and others undocumented. China may be surprised and alarmed that NIAID believes that it is developing biological "weapons of mass destruction". NIAID hopefully pays closer attention to the science of proposals than the political pronouncements of their authors; but it is nevertheless disturbing that biological weapons research spurred by unsubstantiated allegations is being fueled with federal funding. These misperceptions, in turn, may distort what scientists deem "necessary" and "justifiable" as defensive measures as well as what should be available to the public. Other countries, reading such alleged facts in NIAID grants, may be led to regrettable conclusions.

"*Sadly, bioterrorism is no longer an emerging possibility, but rather a daily fact of American life.*"

– Immunetrics, Inc (NIAID Grant 1R41AI052916-01, 2002)

Apropos the previous quote, biological weapons are worrying; but bioterrorism is not a daily fact of any country's life.

"With recent technical progress, it has … become possible for bio-terrorists to create potential pandemic [influenza] *strains faster than natural evolution of the viruses. These threats cannot be sufficiently addressed by the currently available influenza vaccines and antiviral compounds."*

– NexBio, Inc (NIAID Grant 5R43AI056786, 2003)

Despite several US government-funded projects that are developing precisely the technical capabilities that this funded proposal seeks to counter, with the notable exception of a laboratory insider, the realistic possibility of a terrorist creating a novel pandemic influenza strain is, at present, at least a few years away. While improved antivirals would, obviously, be of benefit, the fact that NIAID is funding both the threat and the response (an RNAi approach) raises the question if it has adequately thought through a strategy to deal with the security and health issues raised by modified influenza viruses.

Recommendations, Part 1: Baby Steps

It is the conclusion of this survey that the problems of the Institutional Biosafety Committee system are so severe that it is not effectively accomplishing its current mandate. Much less is the system in a state to be able to absorb the charge of reviewing dual-use research with biological weapons agents.

Renovating or replacing the IBC system with one that can be effective in both biosafety and biological weapons roles will require mandatory rules evenly applied to all institutions. This system must be consistent with internationally-established standards for laboratory safety. These major conclusions of the study are presented in the following section - VIII Recommendations. In addition to the major actions discussed in the next section, a number of smaller measures ("baby steps") can be taken (relatively) easily to renew safety, security, and public accountability of research. These are:

- **Upon receipt of any application for biotechnology research funding by any federal agency, the application should be cross-checked with an up-to-date list of registered and compliant IBCs.** Applications from institutions whose IBCs are not in good standing should, by regulation, be rejected without further consideration. Institutions whose IBCs fall out of compliance in the course of federally-funded research should forfeit grants.

- Similarly, **upon Centers for Disease Control or USDA receipt of any registration document for possession of select agents, the applying institution must be verified as having a registered and compliant IBC**. Applications from institutions whose IBCs are not in good standing should, by regulation, be rejected. Institutions holding select agents whose IBCs fall out of compliance should have their select agent permits revoked.

- **An Ombudsman, reporting to the Director of NIH, should be appointed to monitor IBC compliance and to investigate public complaints and comments on operations of all registered IBCs**. The activities and investigations of the Ombudsman's office should be fully accessible by the public and the attention of the ombudsman should not be divided with other matters. The Ombudsman must be able to compel disclosure by institutions s/he investigates including but not limited to all IBC records, research protocols, adverse event reports, and all records accessible by CDC and/or USDA under the Bioterrorism Act.

- **In NIH's CRISP, and equivalent databases at all other federal agencies funding biological weapons research, a public data field should specify (all of) the IBC(s) responsible for each funded project**.

- **For all extramural biotechnology research, all federal agencies should require a stand-alone Research Assurance Statement** wherein recipient institutions specifically certify compliance with the NIH Guidelines (or their successor, see below).

- **For all intramural biotechnology research, all federal agencies should mandate compliance with the NIH Guidelines (or their successor) by rule**. The agency inspector general should verify that this rule is followed and make public reports, without prejudice to the powers and responsibilities of the Ombudsman.

- **The practice of recruitment of biosafety or research staff of nearby institutions as IBC "community" members should be halted** and IBCs encouraged to incorporate a greater diversity of interests in their membership. IBCs may still choose to include biosafety professionals from other institutions; but not in lieu of more *bona fide* public representatives.

- **The IBC annual reporting requirements to NIH OBA should be expanded and NIH OBA's on-demand access to records enhanced.** IBCs should be required to submit all minutes of all meetings annually, and NIH OBA must establish sound procedures to assess them in order to identify noncompliant or underperforming IBCs. In addition, NIH OBA should have on-demand access to all research protocols, which should be accessible from NIH OBA under the Freedom of Information Act.

- **NIH OBA must establish a more proactive policy of identifying foreseeable technological developments** – particularly in view of the fact that many are federally-funded – and develop procedures for lab safety and dual-use review *as the technologies are foreseen and developed*, rather than several years after the fact, as is presently the case with research on influenza, poxviruses, and other organisms.

VIII MAJOR RECOMMENDATIONS

This survey sought to determine the transparency of 390 institutional biosafety committees, as their public accountability has direct bearing on biological weapons control. In addition, because accountability is an integral feature of the NIH Guidelines and the Asilomar commitment, by assessing the content of minutes and the collective quality of disclosure by IBCs, it was hoped that the survey would also reveal information about the overall health of the IBC system is as it faces NSABB's biological weapons mandate.

While it was anticipated that the survey would raise questions about how detailed IBC minutes should be and what types of information should be contained in them, the process took an unexpected turn when large numbers of IBCs proved unable or unwilling to disclose their activities. That is, the Sunshine Project expected debate over the form and substance of IBC minutes; but it did not anticipate revealing so many dysfunctional IBCs and widespread, overt refusal to comply with the NIH Guidelines. Biotechnology laboratories without registered IBCs, primarily but not exclusively in the government and private sectors, revealed the even deeper problem of the large number of biotechnology and biological weapons facilities that operate outside of the IBC system.

The National Academies of Science and the Bush administration have concluded that IBCs are the appropriate institution-level mechanism to ensure that dual-use biological weapons research does not go terribly wrong. This survey demonstrates that this conclusion is unsound and potentially dangerous. There are yawning gaps in the IBC system: a significant proportion of biological weapons research does not even fall under the purview of an IBC. Even among committees ostensibly operating under the NIH Guidelines and reporting to NIH OBA, disregard for federal recommendations is rampant. While there are exceptions, the notion that research laboratories generally maintain effective, accountable local committees that exercise responsibility over laboratory biosafety is herein demonstrated to be false.

Guidelines and suggestions are not working. The root of the problem lies in the fact that the United States does not have comprehensive laboratory safety law. The system does not even have comprehensive reporting requirements for accidental releases.[38] Although there has been a rash of laboratory accidents reported in the US and abroad in 2003-4,[39] proponents of the IBC system tend to overlook this fact, even as they congratulate themselves that critics worst fears about an accidental release have not been realized. After the anthrax letters of 2001, the same glib attitude is not possible in the case of deliberate release.

The IBC system and, hence, the US approach to review of biological weapons research will only be made effective by making it a matter of law. A regulated system should establish real, enforceable consequences for noncompliance and a level playing field by making binding regulations equally apply to all institutions conducting biological weapons and biotechnology research. This will bring together the fractured oversight of federal laboratories, bring in the private sector, and create more robust and responsible committees in all sectors by providing a sorely needed incentive for compliance. Absent

[38] For example, in 2003-04 Thomas Jefferson University in Philadelphia experienced "*continuing problems with leakage from a BL-3 animal facility into office space*" (TJU IBC minutes, 9 Jan 2004). The IBC responded to the situation by expressing its displeasure about the state of the laboratory in a letter to the Dean. The minutes do not indicate that the lab was shut down on discovery of the problem and do not state that any federal agency was informed. Under the Bioterrorism Act of 2002, accidental releases of select agents do have be reported; but: In 2003, tularemia was unexpectedly discovered in animals in two laboratories at the University of Missouri in Columbia. Tularemia occurs naturally in the region, although the university had concurrent projects in other labs working with the disease. IBC minutes indicate that it reported the problem to the Centers for Disease Control (CDC), however, under the Freedom of Information Act, CDC says that it has no record of the incident. The problem and its causes are thus unrecorded by the federal government.

[39] These include laboratory-acquired SARS infections in Asia, an Ebola death in Russia, an Ebola accident in the US, accidental anthrax releases at a US Army lab, and "dead" anthrax that was in fact live and sent to a children's hospital, also in the US.

these requirements, NSABB mandates are destined to fail because they cannot be practically implemented and enforced.

Finally, while this report focuses on the laboratory biosafety system and biological weapons research in the United States, biotechnology expertise and biological weapons agents are, of course, spread across the globe. Moreover, many biomedical research enterprises operate internationally, particularly biotechnology companies but also universities and others. NIAID's biodefense program is currently funding activities in France, Canada, and Japan. A USDA-sponsored project is making genetically-modified foot and mouth disease in South Africa. US researchers in New York City and Seattle work with (killed) cultures containing Ebola that are provided by a German lab. New strains of avian (and human) influenza isolated in Asia are routinely flown to the United States within hours of their discovery. The spate of high-containment lab construction in the United States is mirrored, although not as aggressively, from Portugal to India. Research even happens beyond any national jurisdiction: Maverick geneticist Craig Venter has a floating biotechnology lab that roams the high seas (and South American territorial waters) in search of new discoveries.

The interconnectedness of science can, of course, be beneficial; but it also demonstrates that no national safety system can effectively stand alone. Currently, the US exports biodefense research on pandemic influenza, Ebola, Lassa, and other viruses to facilities in other countries. These are not countries where those diseases are endemic, they are countries that (presuming a regulatory authority exists that permitted the activity) are willing to accept the research. These facilities, perhaps understandably from their own perspective, do not have IBCs registered with the US National Institutes of Health. While there is no reason to suggest that the investigators in these US-funded projects are deliberately evading the US lab safety system, they demonstrate how it can be done.[40]

Thus, the vastly-improved US laboratory biosafety system that needs to be created must operate in the context of and in harmony with international laboratory biosafety standards. Unfortunately, no such standards exist. The World Health Organization (WHO) has voluntary guidelines and some relevant standards have been established by the World Animal Health Organization (OIE), one of the three standards-setting bodies presently recognized by the World Trade Organization (WTO).[41] The only binding international agreement directly dealing with biotechnology safety is the Cartagena Biosafety Protocol (of the Convention on Biological Diversity), which leaves major areas of "contained use" (i.e. laboratory biosafety) inadequately addressed.[42] Finally, a binding declaration and verification regime under the Biological Weapons Convention would have been a major step toward alleviating concern about dual-use biological weapons research, however, this agreement was blocked by the United States in 2001.[43]

A binding international agreement on laboratory biosafety could complement the Cartagena Biosafety Protocol, build on the work of WTO standards-setting bodies, and achieve at least some of the objectives of the aborted Biological Weapons Convention verification regime. There are serious questions to be resolved in such an agreemen. For example, definitions of containment levels and pathogen risk group assignments vary internationally (not to mention domestically) and, to an extent,

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[40] In this survey, one University of Wisconsin at Madison investigator, who is genetically-engineering pandemic influenza and Ebola with US government funding, repeatedly refused to reveal where this research, which requires BSL-4 containment, is taking place. By alternative sources, the survey ascertained that it takes place in Japan, although UW-Madison and the researcher were unwilling to volunteer this information to the public.

[41] The others are the International Plant Protection Convention (IPPC), which deals with plant pests under the umbrella of FAO and Codex Alimentarius, joint FAO-WHO food safety standards.

[42] See Sunshine Project Backgrounder #11, *Biosafety, Biosecurity, and Bioweapons*, for a more detailed discussion of these agreements.

[43] One critic of the BWC verification agreement memorably called the draft protocol a "house of cards", a term that would in fact be better suited to the NIH Guidelines.

may remain uneven because of the (bio)geography of disease. Technical and financial abilities to implement such standards also varies, including countries where very high-risk agents are endemic while domestic biosafety capacity is low.

Nevertheless, the *laissez-faire* situation actually increases the potential for problems in countries with limited funds and domestic biosafety capacity, because the absence of international standards makes it difficult to monitor and control offshored (and, potentially, domestic) biotechnology research. Moreover, without an international touchstone, national lab biosafety standards adopted by developing countries are particularly vulnerable to WTO challenge as impediments to trade.

For developing countries, this look at the state of the US institutional biosafety committee system may be understood as a stark indication that biotechnology laboratory self-regulation is an unsafe option.

Opinions vary as to whether or not the Asilomar agreement worked in the first place but, as a practical matter, the understanding is indisputably extinct. In an age of biological weapons research, what comes to replace it must accept the realities that developments in biotechnology have made voluntary compliance unachievable and that not even the most powerful nation can go it alone in ensuring safety, good judgment, and peaceful intent.

IX TRANSPARENCY RATINGS BY INSTITUTION[44]

ADEQUATE

(Ranking of 80 or higher on 100 point scale)

Better	*Dana-Farber Cancer Institute*	*Prompt reply, good minutes, if variable in detail.*
	St. Jude Children's Research Hospital	*Though initially reluctant to reply, St. Jude's provided strong minutes, reflecting important discussions in adequate (if uneven) detail.*
Average	*Fenway Community Health*	
	Lawrence Berkeley National Lab (DOE)	
	Oklahoma State University	*OSU's minutes reveal an IBC that is trying hard to address serious problems, many related to (proposed) research on biological weapons agents. While most IBCs would gasp at release of such information, OSU's disclosure reveals that its IBC is serious and diligent.*
	Providence Portland Medical Center	
	University of Nevada Reno	*Aspects of UNR's minutes, such as protocol detail, are lacking; but the IBC's openness (e.g. posting minutes online, discussion of lab construction) is exemplary.*
	University of South Florida	
	University of Virginia	
	University of Wyoming	*Wyoming promptly replied with adequate disclosure (see Biosafety Bites #9). It also sent a hostile cover letter reflecting serious gaps in its understanding of dual-use research.*
	National Cancer Institute Frederick (HHS)	*NCI makes its IBC minutes available online.*
Lagging	*Maine Medical Center*	
	Tampa Bay Research Institute (Showa)	
	University of Louisville	
	University of Pittsburgh	*The University of Pittsburgh's IBC minutes proved to be relatively acceptable, although it required a complaint to NIH OBA to obtain them.*

IN NEED OF IMPROVEMENT

(Ranking of 70 – 79.9)

Better	*Auburn University*	
	Children's Hospital Oakland Research I.	
	Lifespan	
	Rush University Medical Center	
Average	*Columbus Children's Research Institute*	
	Erskine College	*The IBC has seen very little activity, but provided good documentation of what it has done.*
	Marshall University	
	Temple University	
	University of Chicago	*Chicago initially refused to provide its minutes outside of its offices; but capitulated before a formal complaint to NIH OBA. Its evaluation would have been better, were it not for unexplained redactions from its minutes.*

[44] A reminder about the transparency ratings: This evaluation is of the quality of disclosure by the institutional biosafety committee. It is not a judgment of the research that the committee reviews (or doesn't review), nor is it a direct evaluation of biosafety at the institution.

	University of Colorado at Boulder	
	University of Idaho	*Provided reasonably good information about protocol review; but what about the IBC's other responsibilities?*
	Vanderbilt University	
	Virginia Mason Research Ctr. (Benaroya)	*Should have fared better; but large, unexplained black ink reduced evaluation.*
	Western University of Health Sciences	
Lagging	*Florida State University*	
	Fred Hutchinson Cancer Research Center	*Provided a reasonable account of meetings; but didn't reveal what the IBC was discussing.*
	Harbor-UCLA Medical Center	
	Harvard Medical School	
	Medical College of Ohio	
	Research Institute for Children (LSU HSC)	
	St. Elizabeth's Medical Center	
	University of Massachusetts Amherst	
	University of Massachusetts Med. School	
	University of South Dakota	*Highly variable quality of minutes.*
	Yale University	*Could have fared better; but made unexplained redactions, minutes of too limited a scope.*

UNACCEPTABLE

(Ranking of 60 – 69.9)

Better	*Ball State University*	
	Dartmouth College	
	Immunogen, Inc.	
	Pfizer Discovery Technology Center	
	Tufts University	*Provided minutes in electronic format.*
Average	Albert Einstein College of Medicine	
	Blue Sky Biotech	
	Children's Hospital of Pittsburgh	
	Florida Atlantic University	
	Hawaii Biotech Inc	
	Monell Chemical Senses Center	
	New England Biolabs	
	Oak Ridge National Laboratory (DOE)	*Presented obstacles to disclosure, see Biosafety Bites #1*
	Omnigene Bioproducts Inc.	
	Pennsylvania State University	
	San Diego State University	
	Torrey Pines Institute	
	University of Connecticut Storrs	
	University of Washington	*See Biosafety Bites #4*
	Wistar Institute	*Required multiple requests*
Lagging	*Brown University*	
	Childrens National Medical Center	
	City of Hope	
	Millennium Pharmaceuticals	
	Saban Research Institute	
	Scripps Research Institute	

Southern Illinois University	
University of Iowa	
University of Texas HSC Tyler	
US Military HIV Research Program	
West Virginia University	

FAILED

50 – 59.9	Alpha Vax, Inc.	
	Colorado State University	
	Eastern Virginia Medical School	
	George Washington Univ. Medical Ctr.	
	Rocky Mountain Laboratory (HHS)	*Presented obstacles to disclosure. Had recently rebuilt its committee and delayed release of the older IBC's minutes.*
	Illinois State University	
	Jackson Laboratory	
	Kansas State University	
	Massachusetts Institute of Technology	
	Medical University of South Carolina	
	Montana State University	
	North Dakota State University	
	Northern Arizona University	*NAU promptly replied, providing minutes including very little research review. It ignored requests for additional minutes of meetings at which its IBC had reviewed research proposals.*
	Northwestern University	
	Ohio State University	
	Ohio University	
	Old Dominion University	
	Origen Therapeutics	
	Penn State College of Medicine	*Head of the research compliance office replied to the third request for its minutes by asking what NIH Guidelines the survey request referred to. Eventually produced minutes; but with redactions and inadequate protocol descriptions.*
	Saint Louis University	*Site of research including genetic engineering of poxviruses, however, no significant disclosure of these research activities is made in SLU's IBC minutes.*
	Southern Illinois University Carbondale	
	Stowers Institute	
	SUNY - Binghamton	
	University of Alabama Tuscaloosa	
	University of Kentucky	
	University of Michigan	
	University of Minnesota	
	University of Mississippi Medical Ctr.	
	University of Oklahoma HSC	
	University of Tennessee Knoxville	
	Washington State University	
	Wayne State University	

	William and Mary (College of)	
	Wright State University	
	Albany Medical College	
49.9 and lower	American Type Culture Collection	
	Arizona State University	*Promptly replied, providing IBC minutes that primarily addressed administrative matters. Additional minutes that included research review were requested. ASU did not provide them.*
	Battelle Memorial Institute (Columbus)	*Acquiring any documentation on Battelle's IBC required multiple requests and certified mail. In the end, it produced very little. See Biosafety Bites #7.*
	Baylor College of Medicine	*Baylor, a private university, responded by providing minutes with good scope; but poor detail. Baylor redacted its already marginal minutes, citing the Freedom of Information Act, a law that it is not subject to.*
	Boston University Medical Center	*Home of a national BSL-4 biodefense lab to be constructed, BU provided very poor minutes that were heavily redacted. The minutes contained highly inadequate information on protocols and the committee's discussion of them.*
	Brandeis University	
	Brookhaven National Laboratory (DOE)	
	California Institute of Technology	
	Carnegie Mellon	*See Biosafety Bites #11*
	Case Western Reserve University	
	Children's Hospital of Philadelphia	
	Cornell University	*Resisted disclosure and did not produce minutes until after a formal complaint to NIH OBA*
	Duke University	*A very late response and very poor minutes.*
	Duquesne University	*Resisted disclosure and did not produce minutes until after a formal complaint to NIH OBA*
	East Carolina University	
	Emory University School of Medicine	*Emory ignored requests for its IBC minutes and clarification of them, making it difficult for the public to see them at all. The reasons why are discussed in Biosafety Bites #8.*
	Georgetown University Medical Center	
	Idaho National Engineering Lab (DOE)	*The INEL IBC has only met once in its history (in November 2002). It did not review protocols and noted that much unreviewed research is taking place at the facility. It decided to review this and ongoing research; but then never met again.*
	Indiana Univ/Purdue Univ- Indianapolis	*Indiana redacted "information concerning research", "expressions of opinion", "advisory or deliberative material", and information "communicated for the purpose of decision making", rendering completely useless minutes that might have been adequate.*
	Indiana University Bloomington	*IU-Bloomington followed the lead of Indianapolis.*
	Institute for Genomic Research	*A major effort, including certified mail, was required in order to obtain any information about TIGR's IBC. Biosafety Bites #6 makes clear why.*
	Introgen Therapeutics, Inc.	
	Iowa State University	*ISU's response was slow and unfriendly. After a complaint to NIH OBA, as of mid-2004, it has marginally improved disclosure.*
	Johns Hopkins Institutions	*JHU quickly told the press that it would reply to the survey. It did not. After more requests, JHU made minutes available; but*

	created public and private versions of them, without revealing this fact. Edits to the minutes were detected on close inspection. Pressed on the issue, JHU said the differences between its sets of minutes were trivial and eventually provided what it says are its private version (with redactions). JHU's minutes provide much on clinical rDNA projects; but little on any other research. Based on this interaction, the survey concludes that JHU's IBC minutes are subject to manipulations and probably unreliable.
Lawrence Livermore National Lab (DOE)	*LLNL takes the remarkable position of refusing public release of the names of community members of its IBC.*
Los Alamos National Laboratory (DOE)	
Medical College of Georgia	*MCG is open about the state of its committee. Its IBC does not meet to review research, hence, its minutes are very poor.*
Mendel Biotechnology, Inc	
Microbia Inc.	*After its IBC minutes were requested, Microbia's IBC held a meeting (over dinner), thereby generating responsive records.*
North Shore-Long Island Jewish Health	
NE Ohio Universities Coll. of Medicine	
Oregon State University	
Princeton University	*Princeton University's IBC minutes typically present no information about research that it reviews except for a protocol number and an indication that the project was approved.*
Purdue University	
Rutgers University	*Unexplained, large blocks of blacked-out text turn minutes that might have fared well into ones that are essentially useless.*
Sandia National Laboratory (DOE)	
Seattle Biomedical Research Institute	*SBRI's initial reply was a request for Annual Reports and other information from the Sunshine Project (it was provided). SBRI said that it gathers background information on all requesters of its records. It did not offer an explanation for the policy. SBRI's minutes contained inadequate information about IBC reviews and unexplained redactions.*
Serono	
Sidney Kimmel Cancer Center	
Southern Research Institute Birmingham	*After repeated requests, SRI finally produced a list of ongoing rDNA projects that it deems to be minutes of its IBC meetings.*
Southern Research Institute Frederick	*SRI-Frederick's IBC minutes reveal a committee that cannot be said to be fulfilling its obligations under the NIH Guidelines.*
Southwest Fdtn. for Biomedical Research	*SFBR did not produce its IBC minutes until multiple requests were made. Like SRI-Birmingham, the "minutes" are more a list of projects than the records of a functional committee. SFBR's response strongly suggests the presence of classified programs not reflected in the "minutes" provided.*
St. John's University	
Stanford University	
SUNY Stony Brook	*Inadequate minutes made worse by wholesale redactions. Contrary to the NIH Guidelines, Stony Brook considers its IBC minutes "informal" and "intra-agency" records.*
Texas A&M University	*Made minutes available by e-mail; but ease of access does not alter the fact that Texas A&M's IBC minutes contain no information about research under review.*
Texas Tech University	*Texas Tech's IBC minutes are not good, and are centered far more on signing approval forms than earnest review of projects. They also seem to omit a significant Army-sponsored TTU research program on biological weapons agents.*

Thomas Jefferson University	*TJU's IBC identified a persistent problem with containment failure in a BSL-3 lab. In response, the IBC wrote a letter a to the Dean.*
University of Alabama Birmingham	
University of Arizona	
University of Arkansas	
University of Arkansas for Med. Sciences	
University of California Berkeley	*The UC System attempted a coordinated reply to the survey; but its campuses coordinated differently. The reply of its flagship, Berkeley, was the poorest (excepting Santa Cruz, which did not provide an evaluable set of minutes). Possibly except Santa Cruz, all of the UC IBCs appear to operate, which is more than can be said of some state university systems. Some campuses (UCLA,UCSF, Riverside and, to a lesser extent, Davis) maintain reasonably detailed IBC minutes, however, UC schools were heavy-handed and inconsistent in making redactions. Some UC minutes so frequently refer to other documents, that the committee's activities are obscured, greatly lessening the minutes' value.*
University of California Davis	
University of California Irvine	
University of California Los Angeles	
University of California Riverside	
University of California San Diego	
University of California San Francisco	
University of California Santa Barbara	
University of Cincinnati	
University of Colorado Colorado Springs	
University of Connecticut Health Center	
University of Delaware	*Delaware promptly responded to the survey with the most heavily redacted minutes received – pages on end completely blacked out. The University offered no explanation.*
University of Florida	
University of Georgia	*The UGA IBC does not properly operate to review research.*
University of Hawaii Manoa	*The Hawaii IBC's minutes reflect that its overriding concern is servicing the University's relationships with Monsanto, which do not include paying attention to the IBC's biosafety responsibilities– see Biosafety Bites #2.*
University of Illinois Chicago	*Desires BSL-4 lab*
University of Illinois Urbana-Champaign	
University of Maryland Baltimore	
University of Maryland College Park	
University of Missouri Columbia	*Should have fared better as the IBC is active and attends to a wide variety of business, however, like some others in this category, its minutes provide so little detail about research under review that it renders them nearly useless.*
University of New Hampshire	
University of North Carolina Chapel Hill	*UNC did not reply to requests for it to clarify the reasons it blacked-out information that is publicly available on its website from its IBC minutes.*
University of Notre Dame	*Notre Dame's minutes contain nothing about review of research. Asked for additional minutes, from meetings when the committee reviewed proposed projects, it replied that the minutes that contain no information about reviews were the minutes of meetings when the IBC approved protocols.*
University of Oklahoma	
University of Pennsylvania	
University of Rochester	
University of South Carolina	*Ignored multiple requests for its minutes.*
University of Southern California	
University of Tennessee HSC Memphis	

	University of Texas Austin	*No minutes provided by any institution of the University of Texas System were acceptable. Demonstrating a hearty disregard for the public and for the NIH Guidelines, UT Southwestern in Dallas has deliberately structured its IBC records so as to thwart public accountability. Despite a lengthy correspondence with UT Medical Branch in Galveston, home of a BSL-4 and site of a new National Biocontainment Laboratory, its public disclosure remains far from acceptable.*
	University of Texas El Paso	
	University of Texas HSC Houston	
	University of Texas HSC San Antonio	
	University of Texas MD Anderson	
	Univ. of Texas Medical Branch Galveston	
	University of Texas Southwestern	
	University of Utah	*On top of Utah's inadequate IBC minutes, its reply reveals fundamental misunderstandings of law related to biological weapons. Also, it invoked the Freedom of Information Act (which it is not subject to) in order to redact its IBC minutes.*
	University of Vermont	
	University of Wisconsin Madison	*In the 1940s, UW-Madison gave birth to the US offensive biological weapons program. It maintains a large microbiology department and manufactures bioaerosol chambers. Now, while ramping up its research on biological weapons agents, it has decided to halt public IBC meetings and to gut detail from its meeting minutes. UW-Madison also edited information from its older minutes, taken at meetings that were open to the public. Both Wisconsin's lawyers and IBC refuse to substantively discuss their decisions.*
	Utah State University	*Biosafety Bites #11*
	Vical	*Resisted disclosure*
	Virginia Tech University	

UNEVALUABLE TYPE 1 – PREJUDICIAL FINDING

The following institutions did not provide evaluable records and responded in a manner that indicates transparency problems at the institution, a failure to follow the NIH Guidelines, or both:

INSTITUTION	REASON UNEVALUABLE
Donald Danforth Plant Science Center	Held 1st ever committee meeting after request for minutes
ECI Biotech	Provided inappropriate documents, no minutes
Dept. of Veterans Affairs Hines, IL (DOD)	Said it would provide minutes, but did not.
Finch University of the Health Sciences	IBC does not appear to properly function
Georgia Institute of Technology	Committee is in a long-term state of self-organization.
Johnson & Johnson	Presented "minutes" recording that no IBC activity took place
Medical College of Wisconsin	Unable to produce IBC minutes
Medimmune, Inc.	Reports to be "registered voluntarily", refuses to provide minutes
Megan Health (Avant Immunotherapeutics)	Provided admin/procedural-focused minutes, no protocol activity
Monsanto Company (5 IBCs)	Provided unclearly-identified, incomplete sets of minutes.
Mount Sinai School of Medicine	Has no IBC minutes
National Renewable Energy Lab (DOE)	Refuses to provide its IBC minutes
North Carolina State University	Produced a short letter from former IBC chair, has no minutes
North Carolina A&T University	Admin/procedural-focused minutes, no IBC review of protocols
Oregon Health Sciences University	Insists on exorbitant fees for public to have access to minutes
Plum Island Animal Disease Center (DHS)	Replied stating that its IBC has not met in over a year.
Rider University	Says that all rDNA work is exempt from review, no minutes
Rockefeller University	Has no recent minutes, refuses to release other records
Salk Institute	Implausibly claims none of its research requires IBC review
SUNY – Albany	Said it would provide minutes later; but after 7 months, has not
Third Wave Technologies	Refuses to provide IBC minutes
Tulane University	This major research university can produce no IBC minutes
Uniformed Services Univ. Health Sci. (DOD)	Unhelpful to public requesters, stated would reply, did not.
University of Denver	Claims all activity is "electronic", has no minutes

University of Nebraska Medical Center	Has no minutes, demands high fees for other records
University of Sydney (Australia)	Has NIH funding, says local law prevents compliance
USDA ARS Cropping Systems Research Lab	Has no IBC minutes
USDA ARS Ctr. For Ag. Utilization Research	Has no IBC minutes
USDA ARS North Atlantic RRC	Has no IBC minutes
USDA ARS Southern RRC	Has no IBC minutes
Washington University	Refuses to provide its IBC minutes

UNEVALAUBLE TYPE 2 - VARIOUS REASONS

The following institutions replied to the survey; but did not provide evaluable IBC minutes.

INSTITUTION	REASON UNEVALUABLE
Alabama A&M University	Committee is essentially inactive
BallFloraPlant	Committee reported disbanded
Bowling Green State University	Committee inactive for years, now reorganizing
Intermountain Health Care	Committee reported inactive
Lifebridge Health	Committee reported inactive
Marquette University	Committee appears to be brand new
Miami University (OH)	Required open records act, other Ohio schools did not
Mississippi State University	Required open records act, other MS schools did not
Rice University	Committee is essentially inactive
Southwest Oklahoma State University	Provided minutes; but committee is essentially inactive
Texas Woman's University	Committee is essentially inactive
Towson University	Committee is reported as inactive
University Medical Center of Southern Nevada	Committee is reported as inactive
University of California at Santa Cruz	Committee appears to be brand new
University of Kansas Lawrence	Reports that none of its research requires IBC review
University of Maine	Committee is reported inactive
University of North Carolina Charlotte	Committee is essentially inactive
University of Tulsa	Committee is essentially inactive

FAILED TO REPLY

Abbott Bioresearch Center
Abbott Laboratories (IL)
Abgenix, Inc.
Albany Medical College
Albany Regional Cancer Center
Amgen, Inc.
Androscoggin Cardiology Associates
BASF Plant Science Corp (RTP, NC)
BASF Plant Sciences (ExSeed Research) (Ames, IA)
Beth Israel Medical Center
Boston Biomedical Research Institute
Brigham Young University
Buck Institute for Age Research
Bucknell University
California State University Long Beach
Cancer Care Northwest
Cancer Center at GBMC Healthcare
Cancer Centers of Florida
Cardiovascular Consultants of Oregon
Cardiovascular Medical Group of Southern California
Cell Genesys, Inc.
Center for Blood Research, Inc.
Centers for Disease Control
Children's Research Institute
Chiron (Emeryville, CA)
Cincinnati Children's Hospital Medical Center
Clemson University
Cold Spring Harbor Laboratory
Connecticut Agricultural Experiment Station
Corixa Corp.
Cornell University Medical College
CP Kelco
CUNY - Hunter College
CUNY - Queens College
Curis, Inc
Drexel University College of Medicine
DuPont Central Research and Development
East Tennessee State University
Eli Lilly Research Laboratories
Embrex, Inc.
EntreMed, Inc.
Evanston Northwest Healthcare
Genelabs Technologies Inc.
Genencor, Inc. (Palo Alto, CA)

Genencor, Inc. (Rochester, NY)
GenPath Pharmaceuticals Inc.
Genzyme Corporation
Genzyme Corporation (Allston, Ma)
GPC Biotech, Inc.
Hackensack University Medical Center
Highlands Oncology Group
Hope Heart Institute
House Ear Institute
Indiana State University
Iowa Methodist Medical Center
Ithaca College
La Jolla Institute for Allergy and Immunology
Lahey Clinic (MA)
Lenox Hill Hospital
Life Technologies, Inc.
Loma Linda University
Marine Biological Laboratory (Woods Hole, MA)
Mary Crowley Medical Research Center
Maryland Hematology/Oncology Associates
McLaughlin Research Institute
MedStar Research Institute
Meharry Medical College
Melanoma Center of St. Louis
Memorial Sloan-Kettering Cancer Center
Mirus Corporation
New York Blood Center
New York Medical College
New York University School of Medicine
Northeastern University
Northern Illinois University
NovaFlora Inc.
Oklahoma Medical Research Foundation
Oncology Specialists, S.C.
OSI Pharmaceuticals
Pfizer Global Manufacturing (Terre Haute)
Pharmacia & Upjohn (Kalamazoo, MI)
Promega Corp.
PureTech Ventures LLC
Roswell Park Cancer Center
Samuel Roberts Noble Foundation
Schering-Plough Labs (Union, NJ)
Scripps Clinic
Shionogi BioResearch Corp.
Staten Island Urological Research, PC
SUNY Buffalo
SUNY Plattsburgh
SUNY The Research Foundation (Brooklyn)
University of Colorado HSC
University of Massachusetts Boston
University of Massachusetts Worcester
University of Miami School of Medicine
University of Mississippi
University of Missouri Rolla
University of Nebraska Lincoln
University of North Carolina Greensboro
University of Puerto Rico Mayagüez
University of Puerto Rico Medical Sciences Campus
University of Rhode Island
University of Scranton
University of South Alabama College of Medicine
University of Utah School of Medicine
Virginia Commonwealth University
Wake Forest University
Weis Center for Research
Wellesley College
Western Michigan University
Wilkes University
William Beaumont Hospital, Oakland University
Woods Hole Oceanographic Institute

ANNEX 1: BIOSAFETY BITES

Published online between June and September 2004, Biosafety Bites was a short series of case studies from the survey, highlighting particular institutions. The full text of all Biosafety Bites is available online at http://www.sunshine-project.org/biodefense/bb.html. An edited (shortened) version of the 12 Biosafety Bites is printed here.

Biosafety Bites #1 (28 June 2004)

US Army Builds Biodefense Lab, Neglects to Inspect It

A US Army-funded biosafety level three (BSL-3) lab in Tennessee that holds biological weapons agents and is used for biological and chemical weapons studies hasn't had an Army biosafety inspection in three years.

In late 1998, officials at Oak Ridge National Laboratory (ORNL) in Tennessee opened a new BSL-3 laboratory. Located beside ORNL's aerosol chamber, the lab opened new possibilities for ORNL research on biological (and chemical) weapons agents. Built to facilitate research links with the US Army's Dugway Proving Ground in Utah, the Army funded the lab's construction and signed a contract with ORNL that committed it to perform annual inspections to ensure lab safety. In late 1998 or early 1999, ORNL received its first biological agent, botulinum toxin, while work proceeded on chemical weapons agents.

But ORNL's biological expansion drew unflattering attention from the Department of Energy's Inspector General. In a 1999 report, the Inspector General determined that, in addition to financial mismanagement, ORNL had ignored NEPA, the National Environmental Policy Act. NEPA requires environmental review of new federal level 3 and level 4 labs. An embarrassed ORNL replied by saying that it would operate the lab at BSL-2 and that it would give up its "select agent" permit to handle live bioweapons.

At the time, the inspector general dryly - and presciently - noted that "*the Chem-Bio facility was prefabricated to contain a fully functioning Biosafety Level 3 laboratory and that the future microbiological capabilities of the laboratory would not be affected by simply deregistering the facility for live biological weapons agents.*"

Indeed. ORNL's work at the facility with chemical weapons agents was never impaired. And by 2003 (at least), ORNL was back into biosafety level three territory. It is again registered to handle select agents. In fact, it may never have gotten rid of its bioweapons organisms. Earlier this year, a US government report stated that ORNL holds biological weapons agents; but that the precise organisms are classified "secret".(1) At least one of ORNL's bioweapons projects is known - the Chem/Bio Facility, as the BSL-3 is locally-known, is preparing to extract batches of ricin from castor beans.

In December 2003, the ORNL Institutional Biosafety Committee (IBC) reviewed safety at the entire lab, concluding that "*the Chem/Bio Facility continues to operate properly and* [the IBC] *remains comfortable of the review and inspections of the Chem/Bio Facility conducted by the CDC and the Army.*" (CDC=Centers for Disease Control)

Oops.

In early 2004, the Inspector General returned. It turns out that CDC hadn't visited the lab since its commissioning in 1999, and that Army safety inspectors, who were supposed to come every year, hadn't been seen for three years. In effect, the IBC had declared its satisfaction with fictitious safety inspections. And the Army had neglected - for three years running - to ensure the safety of a bio (and chemical) defense lab that it built.

(1) In addition, the facility was described as a BSL-2 lab in this report, the US Confidence Building Measure A for 2004, submitted to the Biological Weapons Convention.

Sources:

DOE Office of the Inspector General, *Inspection of Selected Issues of the Chem-Bio Facility at the Oak Ridge National Laboratory*, November 1999.

Minutes of the ORNL IBC, meetings of 9 July 2003, 12 December 2003, and 23 February 2004.

ORNL Ridgelines (lab newsletter), "The real thing: At last, researchers can work with real chem-bio agents", 12 November 1998.

US Department of State, Confidence Building Measure A, submitted to the Biological Weapons Convention, April 2004.

Biosafety Bites #2 (29 June 2004)

Tropical Disaster: The University of Hawaii Institutional Biosafety Committee

The University of Hawaii (UH) may be 2500 miles (4000km) from the west coast; but its Pacific location hasn't hurt its biotechnology research programs, which are the islands' largest. Manoa, the main UH research campus, has 20,000 students and attracts major federal research funding. UH has large-scale biological programs at its medical school, college of agriculture, and in related centers. UH operates biosafety level three labs and works with potential biological weapons agents, as defined by the Centers for Disease Control ("select agents") and the US Department of Agriculture ("high consequence pathogens")

Among UH's many research projects is its NIH-funded Pacific Center for Emerging Infectious Disease Research. UH develops high-profile biotechnology: In 1999, it boasted of having produced the "first male clone" (a mouse). Its website offers licenses for a technology to produce an experimental recombinant vaccine in silkworms. One UH lab is dedicated to technologies for the large scale production of recombinant proteins in bioreactors. With so much research activity at UH, one might expect its IBC to be busy with the business of biosafety. Think again. According to documents provided to the Sunshine Project by the University of Hawaii, the business that the UH IBC is occupied with is the Monsanto Corporation.

In the past eight months, the UH IBC has met twice. The record of the first meeting, in November 2003, is titled "Meeting with Monsanto". At the hour and half-long meeting, whose minutes consist of less than a half a page, Monsanto and Hawaii told each other that they enjoy working together and that they will each comply with applicable rules. There is no review of research, no review of lab conditions, and no real biosafety business recorded concerning the Monsanto arrangement, much less other research going on anywhere else at UH. At its only meeting since, in March 2004 and titled "Pre-Commercialization/Commercialization", the UH Institutional Biosafety Committee discussed a researcher's need for IBC support for his commercialized recombinant papaya, a project that also involves a relationship with Monsanto. Supporting commercialized genetically-engineered crops is a curious choice of business for an IBC. IBCs deal with biological containment, not transgenics released for sale, which are, by definition, not contained. Again, no real biosafety business is recorded.

Federal rules require UH to release its IBC meeting minutes to the public, but it resisted doing so. When UH consented to provide records of its meetings, after several requests over the first half of 2004, it claimed that minutes of the November 2003 and March 2004 meetings are the only ones that exist. UH explained this by saying that its IBC didn't start taking meeting minutes until after the National Institutes of Health (NIH) issued guidance to IBCs on minute-taking. The problem with UH's response is that the NIH document was issued in May 2004, months after the IBC meetings took place.

Making its position even more dubious, the minutes UH provided state that its IBC reviewed and adopted additional minutes taken at meetings prior to November 2003. But UH's cover letter says that these minutes don't exist, because its IBC didn't take minutes before November 2003. In short, either UH's IBC minutes are a fabrication, or it knowingly responded falsely. Either way, UH's credibility is not high.

In recent correspondence, the Assistant Vice President for Research of the University of Hawaii has promised to produce more information concerning the UH IBC. The NIH Office of Biotechnology Activities, which oversees the UH IBC, has been alerted to the information contained here; but has not, to the Sunshine Project's knowledge, taken any action. Further developments with the UH IBC will be discussed in future Biosafety Bites or the final report of the Sunshine Project IBC survey.

[*Note to readers: At the time of publication of this survey, UH has not provided the additional information*.]

SOURCES:

Documents purported by the University of Hawaii to be the minutes of its Institutional Biosafety Committee meetings of 20 November 2003 and 27 March 2004.

E-mail from Frank O. Perkins, Assistant Vice President for Research of the University of Hawaii, 25 June 2004.

Letters from James T. Douglas, Chair, University of Hawaii Institutional Biosafety Committee, 4 February 2004 and 17 June 2004.

University of Hawaii Environmental Health and Safety Office, Forms BSP-1-5 (http://www.hawaii.edu/ehso/bio/)

Biosafety Bites #3 (6 July 2004)

Moribund: The Department of Homeland Security's Plum Island Biosafety Committee

Few, if any, biodefense research facilities have had as controversial a relationship with neighbors as the Plum Island Animal Disease Center, a large biosafety level three lab located on a small island in New York. In the Long Island Sound between New York and Connecticut shores, Plum Island was originally slated to be a US Army chemical weapons lab. In the 1950s, however, it passed to the US Department of Agriculture and became USDA's primary research lab on exotic animal diseases, such as African swine fever and foot and mouth disease. In 1999 and again in 2002, USDA tried to upgrade Plum Island to biosafety level four. Each time, the USDA was stymied by local opposition that has been remarkably effective at mobilizing its elected officials' influence in Washington. (1)

Things are changing, however, and on June 1st, 2003, Plum Island got a new owner. Since assuming control, the US Department of Homeland Security (DHS) has been coy about its plans, saying that it does not plan a BSL-4; but that Plum Island has a significant role in DHS' highly controversial biological weapons "threat characterization" agenda. (2) Recently, DHS revealed that Plum Island will be renovated and re-christened as the Department's Agricultural Biodefense Center (ABC).

On the face of it, DHS says it is "committed to positive community relations"; but in a recently-published notice in the Federal Register, it proposed to grant itself authority to make secret the environmental assessments of government activities that are required by the National Environmental Policy Act (NEPA). The change would make it possible for DHS to conduct activities on Plum Island (and other facilities) without divulging risks, effects or even their existence under NEPA. Plum Island is poised on the bleeding edge of DHS' research program on biological weapons, a program that includes activities that independent observers conclude are practically indistinguishable from offensive biological weapons research.

Which brings us back to Plum Island's institutional biosafety committee (IBC), the local committee that, according to the Bush administration, forms the government's major line of defense to review dual-use research projects and to ensure their safety and security. Thus, if there is a place where the government might demonstrate that IBCs can in fact be an effective mechanism to review the conduct of dual-use bioweapons research, it is at facilities like Plum Island, which are under direct government control and which have missions that are focused on biodefense.

What has DHS done with the Plum Island Institutional Biosafety Committee? Nothing. Since DHS took over the facility more than a year ago, the Plum Island IBC has not met. Not once. The committee whose responsibility it is to ensure that research is safe and secure appears to be moribund. Not only has there been no committee review of Plum Island's new and ongoing research projects, the committee has not met to review safety conditions in laboratories nor to perform any of the other duties incumbent upon it.

NOTES AND SOURCES:

(1) Although USDA never built a lab with full BSL-4 containment in Plum Island, it did develop a type of enhanced BSL-3 containment for large animals for the Plum Island facility. Called "BSL-3ag", the Plum Island facility has some characteristics of BSL-4 labs not typically found at BSL-3 facilities.

(2) For a discussion, see Ruppe, David "Proposed U.S. Biological Research Could Challenge Treaty Restrictions, Experts Charge", Global Security Newswire, 30 June 2004 (http://www.nti.org/d_newswire/issues/2004_6_30.html)

DHS. Fact Sheet: Plum Island Animal Disease Center Transition, http://www.dhs.gov/dhspublic/display?theme=27&content=937

DHS. Response to Sunshine Project information request, FOIA case 04-459, 21 June 2004.

DHS Environmental Planning Program. Notice of proposed directive, request for comments. See: http://www.dhs.gov/dhspublic/interweb/assetlibrary/MD5100-106-01-04.pdf

Also see the website of the NSABB, http://www.biosecurityboard.gov

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Biosafety Bites #4 (12 July 2004)

Incautious University of Washington Bends Biosafety in 1918 "Spanish" Flu Experiments

It's back from the dead. It packs a lethal punch. It's the 1918 "Spanish" Flu virus. (1) The 1918 flu was recently brought back to life by scientists from the US Departments of Defense and Agriculture, and private institutions including the Mt. Sinai School of Medicine in New York. Digging through archives of medical samples and, literally, digging up the

dead, the team's work resulted in the re-emergence - in the lab - of one of the most dreaded diseases in human history.

The 1918 flu was recreated at a lab at the University of Georgia. Now, flu strains with 1918 genes are cropping up in other labs across the country. There are reasons for scientists to study why the 1918 flu was so devastating. A similarly virulent strain could reappear naturally. But a need to understand why 1918 flu was so devastating doesn't necessarily justify recreating and widely distributing a very dangerous - and otherwise eradicated - bug.

Things got off to a bad start with the 1918 influenza. When it was recreated, neither the US Department of Agriculture nor the University of Georgia (the institutions in charge of the Georgia lab) bothered to have an IBC review the experiments. (2)

In Seattle, University of Washington (UW) researchers are gearing up for some of the most ambitious experiments yet undertaken with 1918 influenza. UW will work with the previously recreated 1918 flu and make more types by inserting up to five 1918 genes into a similar (H1N1) but less dangerous type of flu that was isolated in Texas in 1991 (there are only six gene-containing plasmids in the influenza genome). UW researchers' plans include culturing 1918 viruses, infecting animal cell lines with them, isolating samples after such 'passages' and, in the course of research, shuffle through the lab with various biological materials and equipment containing live 1918 flu types.

The objective is to develop and research a non-human primate (Pigtail macaque) model for 1918 influenza infection. In other words, the experiments will culminate by UW spraying lab monkeys with genetically engineered 1918/Texas flu and recording the results. The macaques might rather be home in Southeast Asia; but the hope is that using them as models for human infection with 1918 flu will provide useful information for managing flu outbreaks, either natural or deliberate.

But the University of Washington doesn't have an appropriately facility for the studies and its IBC isn't at all clear or vigorous in implementing necessary safety protocols.

The UW IBC's approval of Spanish flu experiments is, however, critical for the projects to receive federal funding. So, in August 2003, the UW IBC took up the matter. The first problem it encountered was that the animal biosafety level three (ABSL-3) facility where the experiments were to take place hasn't been built. Secondly, USDA, which was providing the 1918 influenza, had classified it as requiring BSL-3ag containment.(4) BSL-3ag is a more stringent standard than that of existing UW labs and the planned ABSL-3 lab. BSL-3ag is just one step short of maximum containment BSL-4, the level that a cautious institution might have assigned the 1918 constructs in the first place. (Neither USDA nor Georgia, however, have a BSL-4 lab.)

Apparently unwilling to hold its researchers back over biosafety issues, and despite the lack of adequate facilities, the UW IBC approved 1918 flu projects. It has allowed some activities to go forward in an existing (non-animal) BSL-3 facility, despite USDA's BSL-3ag designation of the agent. Remarkably, the UW IBC also decided, on the spot, to change the biosafety level of the new UW lab. The IBC decided that the new lab, previously not intended to be BSL-3ag, would meet the more stringent designation "in principle". This dubious endorsement enabled grant applications to move forward and for UW researchers to proceed to acquire the 1918 flu from USDA, with the "in principle" UW BSL-3ag lab.

After "resolving" the problem of not having appropriate containment, the UW IBC then considered the operating procedures to be followed in the existing BSL-3 lab for 1918 flu experiments. Here, the "culture of responsibility" of the UW IBC again failed.

The benchmark that the UW IBC referred to for 1918 flu safety were procedures used to handle human immunodeficiency virus (HIV). But the virus that causes AIDS is relatively difficult to transmit, especially by aerosol, the main cause for concern with influenza. Moreover, the risk to the community posed by a lab-acquired HIV infection is trivial in comparison to the threat posed to the world by a case of potentially pandemic influenza.

The UW IBC only considered one of the many opportunities for influenza aerosolization in the studies, that if a tray were dropped. In such an event, the UW IBC decided that researchers "will be trained to stop breathing... just as they are taught to do when working with HIV". An independent microbiologist who the Sunshine Project provided a copy of the UW IBC minutes called the UW biosafety protocols in the 1918 project to be "inappropriate" and "risible".

The minutes of the UW IBC also suggest - but don't entirely clarify - that UW researchers, already working at a lower level of containment than that assigned by USDA, may plan to place cultures infected with 1918 influenza in an unshielded centrifuge. Because their spinning energy can rapidly aerosolize liquids, centrifuges are a notorious source of laboratory infections.

UW's irresponsible treatment of biosafety in the 1918 influenza project does not appear to bother the National Institute of Allergy and Infectious Disease (NIAID). NIAID recently funded the project. Its formal start date was the beginning of this month, July 1st, 2004.(5)

Notes and Sources

(1) The 1918 influenza strain is popularly called "Spanish" influenza, based on incorrect suspicions about its origin at the time of the outbreak. In fact, to this day, there is no scientific consensus on the origin of the strain.

(2) USDA Agricultural Research Service reply, dated 2 October 2003, to Sunshine Project FOIA of 11 August 2003, for minutes of the IBC meeting that reviewed 1918 influenza experiments. Personal communication with Daryl Rowe, Institutional Biosafety Officer, University of Georgia, September 2003.

(4) How USDA and/or Georgia determined BSL-3ag containment, which is stated in the UW IBC minutes and NIH grant abstracts, is unclear. As indicated in note 3, under FOIA, USDA asserts that no IBC ever reviewed the project to re-create 1918 influenza.

(5) NIH Grant 1P01AI058113-01 to the Mt. Sinai School of Medicine includes the UW component for 1918 influenza studies.

Other sources:

Minutes of the University of Washington Institutional Biosafety Committee, meetings of 2 December 2002 and 22 August 2003.

Baskin CR et al. Gene Expression Control in Pigtail Macaques Infected with Influenza A/Texas/36/91: A PILOT STUDY. Innate Immune Response and Patterns of Immune Cell Migration in an Uncomplicated Influenza Infection, online poster submission for the Fifth Annual Northwest Gene Expression Conference, to be held at the University of Washington, 25-27 May 2005. URL: http://ra.microslu.washington.edu/Website/nwgec/posters/postersubmit.html

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Biosafety Bites #5 (19 July 2004)

No Biosafety Meetings at Rockefeller University

The Rockefeller University isn't your average college named after a rich guy. Located in New York City, it is wealthy, elite, and focused solely on biomedical research. Rockefeller has reason to be proud. It has been associated with no less than 32 Nobel laureates, and boasts of having achieved major research advances, including discovering that DNA is the basic material of heredity, determining that cancer can be caused by a virus, confirming the connection between cholesterol and heart disease, and developing "cocktail" drug therapy for AIDS.

Rockefeller researchers are also leaders in biodefense. They have political clout and advised the top levels of the US government on biological weapons issues for decades. In the lab, the University is currently leading studies on anthrax and plague as part of NIH's crash program to develop responses for the newfound US fear of biological terrorism.

Back in March 1998, it was a more optimistic time than now. Biosafety was out of vogue and out of mind. Even at one of the world's most prestigious biomedical research centers, worries were uncommon.

On March 26th, 1998, the Rockefeller University Institutional Biosafety Committee (IBC) held what appears to have been its last-ever regular meeting. There was no outstanding business to discuss and only one new project that the committee felt merited review. According to the meeting's minutes, exactly three committee members were present – the rest signed off without a meeting and didn't bother to attend. A single committee member, an expert in circadian rhythms, was reluctant to approve the project that had been tabled. It was a gene therapy experiment involving injecting genetically modified adenoviruses into human volunteers. The possible dangers were unclear. The dissenter stood his ground; but the final fate of the experiment isn't clear, because the committee never met to consider it again.

The Rockefeller IBC didn't meet again until September 23rd, 2003. But that was even less of a proper meeting than the last one - five and a half years before. In 2003, it examined a single project, involving injection of DNA into cancer patients, and determined that the project did not involve gene transfer, as defined by the National Institutes of Health. So there was nothing to discuss. End of story. The committee hasn't met since.

The University did not reply to the first request for minutes of its IBC meetings. After a second request, Rockefeller still did not provide any minutes, instead it peremptorily insisted that the Sunshine Project declare it had "cooperated fully" with the Project's survey of IBCs – in the absence of any substantive response. A third request was ignored. A fourth request resulted in a hostile letter from Rockefeller's former biological safety officer.

Finally, after additional haggling by electronic mail involving copies sent to NIH regulators and senior Rockefeller

professors, after five and half months of delay, Rockefeller produced the minutes of the two most recent meetings of it Institutional Biosafety Committee – those of September 2003, and... March 1998.

In its defense, Rockefeller says that its IBC usually "conducts its business electronically", meaning that it says handles biosafety by e-mail and doesn't take any minutes of its proceedings. But it refuses to provide any of the e-mails. It is thus not only impossible to verify Rockefeller's claim; but frankly difficult to fathom how, over more than six years, the Rockefeller IBC has only once encountered a biosafety issue that merited a face to face discussion by the committee that has ultimate responsibility over the safety of its biotechnology research. (And the one meeting, as mentioned above, was perfunctory.)

Rockefeller University isn't the only embarrassed owner of a dysfunctional IBC, although the failure of its committee to even meet – for years - is particularly glaring considering the prestige of the institution. These same IBCs are, according to the Bush administration, to be placed in charge of reviewing the conduct of dual-use research with biological weapons agents. Senior administration officials say that, in lieu of regulation, IBCs can adequately manage the conduct of biodefense research. But the IBC system lacks legal teeth and can't adequately handle the jobs it presently has. How, then, can it possibly rise to the greater charge of ensuring health, safety, and good judgment in the conduct of dual-use biological weapons research?

Sources:

Minutes of the Rockefeller University IBC, 23 September 2003 and 26 March 1998.

Sunshine Project Correspondence with Rockefeller University officials, 30 January 2003 through 15 July 2004.

Biosafety Bites #6 (27 July 2004)

The Institute for Genomic Research: Genomic Powerhouse, Biosafety Tragedy

The Institute for Genomic Research (TIGR), based on Maryland's "biotech corridor" northwest of Washington, DC, is a non-profit powerhouse of genomics. TIGR has led in the sequencing of microbial genomes, particularly of human and animal diseases.

Active in biodefense for many years, in late 2001, it jumped in with both feet. It performed genetic analysis of spores from the anthrax letters, fingering a US biodefense lab as the likely source of the strain. TIGR biodefense projects include work with valley fever (*Coccidiodes immitis*), Q fever (*Coxiella burnetti*), and brucella (*B. suis*). In one National Institutes of Health-funded project begun in mid-2003, a TIGR scientist is tweaking the virulence genes *Burkholderia mallei*, the bacteria that causes glanders, a disease that naturally primarily affects horses; but which is a potent biological weapons agent that can infect humans and has been weaponized in the past. The genetically-engineered bacteria with altered virulence are then introduced into mice and hamsters.

With assets of nearly US $200 million and annual revenues over US $40 million, the well-funded and well-connected TIGR scientific team operates without many of the financial and market pressures acutely felt in other academic and commercial labs. While its privileged situation would seem to mitigate for increased attention to its institutional biosafety committee (IBC), the tragic reality is that since TIGR was founded in 1992, the TIGR IBC has only met twice, once in 2002 and once in 2004. Each meeting lasted one hour, for a total of two hours face time in twelve years - or, on average, ten minutes per year that the TIGR IBC meets to perform its duties.

During its entire existence, the TIGR IBC has examined exactly two projects, both in 2002, quickly deciding that each was exempt from full committee review under the NIH Guidelines, and thereupon halting its discussion. When the committee met in 2004, it only came together to review the format of its paperwork. It did not review any research projects, much less any other aspect of biosafety at TIGR.

Despite the requirements of the NIH Guidelines, it was only after the Sunshine Project began sending copies of its correspondence to the National Institutes of Health that TIGR decided to reply at all to the Sunshine Project's requests. The committee meeting of 2004, on April 23rd, at which no real biosafety business transpired, took place almost three months after the Sunshine Project began to request TIGR's IBC minutes; but before TIGR replied to the Sunshine Project's requests.

In correspondence with the TIGR IBC Chair, the Sunshine Project directly raised the question of TIGR research with biological weapons agents that has not been reviewed at an IBC meeting. TIGR's IBC Chair initially said that he could

not reply promptly because he needed to file grant applications. He then sent a letter ignoring the question; but which, after six months of Sunshine Project queries, finally clarified that the TIGR IBC has only met twice in its history.

[Note to Readers: Although TIGR refused to elaborate with the Sunshine Project, after this Biosafety Bites was published, in response to a journalist's inquiry, it stated that the glanders project is being conducted off-site and, thus, its IBC did not review it. TIGR did not state where it is conducting this work.]

Sources:

Correspondence with Najib M. El-Sayed, Chair TIGR IBC, January - July 2004.

Minutes of the TIGR IBC, meetings of 6 March 2002 and 23 April 2004.

TIGR Internal Revenue Service Form 990 (non-profit tax return), fiscal year 2002.

NIH CRISP database, grant abstracts for TIGR.

Biosafety Bites #7 (10 August 2004)

No Functional Biosafety Committee at Battelle Memorial Institute

Battelle Memorial Institute, headquartered in Columbus, Ohio, is a gigantic science contractor with an emphasis on defense research, including classified programs. Battelle has offices across the US - often near Department of Defense facilities - as well as business in at least six foreign countries. Battelle operates four US Department of Energy-owned laboratories,(1) each of which conducts biotechnology research. Battelle also has its own in-house BSL-3 facility, at West Jefferson, Ohio, which is reported to conduct classified biodefense research for the US government.

Battelle is overwhelmingly funded by the US government, which provides it with US $1.3 billion per year in grants, plus hundreds of millions in payments for services. Technically a non-profit organization, Battelle is an unusual 'charity'. It pays a seven-figure salary to its director, controls more than two dozen for-profit spin-off companies, and dispenses grants to nonprofit organizations near its facilities, such as the Columbus Zoo, in a manner similar to corporate sponsorship.

While Battelle is a colossal enterprise, its institutional biosafety committee (IBC) is not. In fact, for a period covering four and a half years (since 1 January 2000), Battelle cannot produce a single page of minutes of IBC meetings. In the same time period, Battelle has only once reported to the NIH Office of Biotechnology Activities. The late 2001 report was made shortly after the *New York Times* ran a story saying that Battelle would be the site of a project to genetically engineer a vaccine-resistant strain of anthrax. The "report" merely consists of a single page listing IBC members, and attaching their resumes, and informs NIH that Battelle "has established" an IBC. The "report" strongly suggests that the Battelle IBC did not exist until after the institute's involvement in classified biodefense studies was widely reported.

Battelle did not answer the Sunshine Project's January request for its IBC minutes. Battelle replied to a follow-up letter, sent by certified mail in May, by saying its IBC hasn't met since June 1st, 2003. Battelle replied to a third request - this time for all IBC minutes and all reports to NIH since January 1, 2000 - by providing a single, heavily redacted page of paper - the late 2001 letter it submitted to NIH, informing the Office of Biotechnology Activities that it "has established" an IBC. (2)

Battelle's final reply to the Sunshine Project, however, curiously states that "Battelle's IBC has been inactive [since January 1, 2000], except for review of one project, for which no IBC documents are available for release to the public." It is possible that this project, documentation of which Battelle refuses to provide, is the anthrax genetic engineering effort, although that project is only one of many involving recombinant DNA that Battelle conducts.

In sum, Battelle's institutional biosafety committee does not meet, does not report to the NIH Office of Biotechnology Activities, does not review projects, and does not take responsibility for lab safety. Rather, its IBC is decorative – a slight, cynical gesture in the direction of the NIH Guidelines.

NOTES

(1) The labs operated by Battelle are Brookhaven, Oak Ridge, and Pacific Northwest National Labs, as well as the National Renewable Energy Lab (NREL). These labs have NIH-registered IBCs, although one (Pacific Northwest) is brand new and another (NREL) refuses to comply with the NIH Guidelines public access provisions. Oak Ridge's IBC was the subject of Biosafety Bites #1.

(2) Battelle did not maintain a copy of this "report" to NIH. The redacted cover letter received by the Sunshine Project bears a NIH received stamp, indicating that Battelle had to ask NIH for a copy of its own "report" in order to provide it to the Sunshine Project.

SOURCES

Battelle Annual Report 2003

Correspondence with Adam Wagenbach and Donald Cagle of Battelle, January – August, 2004.

Battelle Internal Revenue Service Form 990 (non-profit tax return), fiscal year 2002.

Biosafety Bites #8 (12 August 2004)

No Biosafety Reviews at Emory University

Emory University in Atlanta, Georgia, is a biomedical research powerhouse. It has approximately 1.3 million square feet (120,000 square meters) of research laboratory space, 600 biological safety cabinets, a primate research center, and several BSL-3 labs scattered across its suburban campus. Many of those labs are occupied with biodefense research. In NIH-funded studies, Emory scientists are researching vaccines for smallpox, Ebola, Rift Valley Fever and Lassa viruses, and studying anthrax. Emory scientists are genetically-engineering measles, Yellow Fever, and other viruses in attempts to produce a vaccine against AIDS. Some Emory projects are closely linked to research at the US Centers for Disease Control, also in Atlanta.

Emory University's Institutional Biosafety Committee has not reviewed any projects in at least four years. Not a single protocol from Emory's large portfolio of biodefense and genetic engineering research has received a moment's consideration at a biosafety committee meeting. In fact, since 2001, the Emory IBC has only met three times, less than once per year. The last Emory IBC meeting occurred in July 2003, when one third of the committee's members played hooky, leaving only 11 of 16 members in attendance.(1)

In addition to being charged with biosafety responsibility, Emory's IBC (locally called the "Health and Biosafety Committee") also handles chemical and radiological issues. Thus, even when the committee has actually met, its attention has been divided. At none of its meetings since 2001 has the Emory IBC reviewed biosafety of any project. Instead, Emory's IBC hears general presentations from staff about biological, chemical, and radiological safety. The minutes of Emory's meetings indicate that, after hearing the presentations, members of the IBC have only rarely had any questions or comments to make, for example, this passage from the minutes of the committee's 2001 meeting: "*Comments and Questions from the Committee: There were not any comments and/or questions*. [The Chair] *thanked everyone for attending the meeting*." (2)

The Sunshine Project had difficulty obtaining Emory's IBC minutes, despite the NIH Guidelines. Emory did not respond to the Project's initial inquiry. It was only after a full six months, and correspondence that involved copies sent to NIH staff and by certified mail, that Emory finally produced a full set of its IBC minutes.

Prior to this Biosafety Bites, the Sunshine Project offered Emory's Associate Vice President the opportunity to explain why the Emory IBC does not review any proposed research, a particularly disturbing situation in view of Emory's huge biomedical research portfolio. Emory's defense, which was presented in a letter consisting of two sentences, is essentially to admit that its IBC is derelict in its duties. According to the University, "*Designated IBC committee members review all protocols requiring IBC review*."

Emory produced no record of any these alleged reviews and none of the research protocols or reviews are even mentioned, much less discussed, at its actual IBC meetings. Nor did the Associate Vice President even attempt to explain how the Emory IBC's total abdication of responsibility for project review can be squared with the NIH Guidelines.

NOTES

(1) Minutes prior to those of 22 July 2003 list only those members present and do not list members who were absent.

(2) Emory University IBC Minutes of 12 April 2001.

SOURCES

Correspondence with Kristin West, Associate Vice President, and Robin Lutrell, Biological Safety Officer, Emory University, January - July 2004.

Minutes of the Emory University Institutional Biosafety Committee, 12 April 2002, 20 June 2002, and 22 July 2003.

Biosafety Bites #9 (13 August 2004)

USDA's 'West St. Louis Virus'

This summer, fear of the West Nile Virus (WNV) epidemic grips much of the northern hemisphere. This week WNV was confirmed in Portugal. The virus has recently been confirmed in Siberia, and it continues to establish itself in many areas of the United States.

A team of US Department of Agriculture (USDA) scientists is taking a dubious approach to combating the problem. At the University of Wyoming, USDA researchers are trying to create new, pathogenic types of WNV that could prove to be worse than the naturally occurring virus. USDA is doing this by crossing West Nile with St. Louis Encephalitis (SLE), a related flavivirus that is endemic to the US but that presently infects far fewer people each year. (1)

The two viruses are not known to naturally cross, and a prior study done elsewhere suggested that the possibility is not high. Rationalizing that it still might happen, however, the USDA researchers are forcing the issue by forcing WNV and SLE to recombine. The researchers will isolate lab-created WNV-SLE hybrids ("West St. Louis Virus") and then plan to infect mosquitoes, birds, and lab mice with the engineered viruses. They then plan to study the results, characterizing the pathogenicity and host range of the novel viruses. They will also develop a diagnostic test to detect the bugs which, insofar has been established by research, will only exist in the lab in Wyoming.

USDA is performing this research at the University of Wyoming because BSL-3 animal facilities at its own lab in Laramie, the Arthropod-Borne Animal Diseases Research Laboratory (ABADRL), were closed for emergency repairs in 2003.

USDA is thus deliberately making novel, lethal viruses with epidemic potential for humans (and animals). Its specific intent is to create, isolate, culture, characterize, and study transmission of a new and deadly disease. USDA is doing this at a university lab because its own facilities are broken. Not only will a containment failure in these experiments pose a serious public health threat; but also there is limited scientific justification for experiments, and they raise questions about the US biodefense program and the Biological Weapons Convention. What if other countries start government programs to create designer disease citing similar rationales?

When weighed against the risks that the experiments generate, there is ample room to question whether 'West St. Louis Virus' should be created at all. Certainly, this USDA project, like a number of other biodefense experiments to deliberates create disease, such as reconstituted 1918 "Spanish" influenza, present public, policy, arms control, and scientific issues that deserve extremely careful review before the project is conducted (or discarded as unnecessary, unsafe, unwise, or unlawful).

But USDA's ABADRL does not have a registered Institutional Biosafety Committee. Thus, it was only because the condition of USDA's labs forced it to move the experiments onto the Wyoming campus that they were reviewed by a registered IBC at all.

NOTES

(1) According to the Centers for Disease control, the US averages 128 human cases of St. Louis Encephalitis each year. The virus can cause paralysis and is fatal in 3-30% of cases. (See http://www.cdc.gov/ncidod/dvbid/arbor/sle_qa.htm)

SOURCES

Minutes of the University of Wyoming Institutional Biosafety Committee, 17 April 2003.

Biosafety Bites #10 (18 August 2004)

Tulane University's Broken Biosafety Committee

Tulane University in New Orleans, Louisiana is a major biomedical research center. Tulane operates BSL-3 facilities in New Orleans and is a partner in both the Western Regional "Center of Excellence" in Biodefense (led by the University of Texas Medical Branch in Galveston), and the Southeast Regional "Center of Excellence" (led by Duke University in Durham, NC). Both centers are funded by the National Institutes of Allergy and Infectious Disease (NIAID).

Several Tulane scientists have leapt into biodefense studies. These include one whose grant application states as a matter of fact that China, Syria, and other countries have offensive biological 'weapons of mass destruction' programs. NIAID funded it. Tulane scientists are working with anthrax, plague, and other biological weapons agents.

The Tulane National Primate Research Center (TNPRC), located in Covington, LA, is a research facility housing 5,000 monkeys for biomedical studies. In 2003, TNPRC received a regional biocontainment laboratory grant from NIAID, enabling it to build a large new BSL-3 biodefense facility. Three BSL-3 laboratories are already in operation at TNPRC, and new primate aerosol facilities are being developed. One of the first projects planned for the aerosol facility are pathogenesis studies involving spraying macaques with the biological weapons agent brucella.

So if the Bush administration and the National Academies of Science are right when they say that the alleged 'culture of responsibility' of Institutional Biosafety Committees is sufficient to ensure safety, security, and good judgment in biodefense research, then Tulane University is clearly a place where a healthy and robust IBC should be found. After all, NIAID is heavily funding Tulane to work with biological weapons agents and, particularly, to develop its capacity to run biological weapons aerosol challenge studies on large primates.

But when asked for all minutes of all meetings of its IBC since January 1st, 2002, Tulane replied that it has no responsive documents. That is, Tulane University cannot produce a single page of minutes of any Institutional Biosafety Committee meeting for the past two and half years. Tulane was most unforthcoming about its IBC's inactivity. Tulane did not reply to a faxed request and ignored a request sent by certified mail. It was not until the Sunshine Project contacted several people at Tulane and sent copies of the correspondence to the National Institutes of Health that the University confessed to its IBC's inactivity. It did so in a letter consisting of three terse sentences.

Remarkably, and perhaps most indicative of Tulane's attitude about its IBC, is that the University didn't even schedule an IBC meeting a produce a perfunctory set of minutes after the Sunshine Project's initial, smaller request in January. That is, Tulane had more than four months to activate its IBC after it became aware that the Sunshine Project insisted on copies of the committee's minutes. Instead, it simply ignored requests until July, when pressure finally forced it to admit that it had no minutes.

SOURCES

Letter to the Sunshine Project from James J. Balsamo, Director, Tulane Office of Environmental Health and Safety, 8 July 2004.

Region VI Center for Biodefense and Emerging Infections (grant application to NIAID), University of Texas Medical Branch, January 2003. (Obtained under the Texas Public Information Act.)

NIH CRISP database, abstracts for NIAID awards to Tulane University. (See 1R21AI055013 re China and Syria.)

Biosafety Bites #11 (3 September 2004)

Asleep at the Wheel? The NIH Office of Biotechnology Activities

The Sunshine Project has filed ten new complaints against US research institutions that do not maintain institutional biosafety committees as required under the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (the NIH Guidelines). The causes for the complaints range from an IBC that approved dozens of projects without actually meeting (ever), to IBCs that, despite explicit instructions from NIH, continue to resist release of records that "shall be made available" to the public.

It remains to be seen if NIH's Office of Biotechnology Activities (OBA), which is in charge of the NIH Guidelines, will take action in the new cases. OBA has remained stoically silent over 2004, a tumultuous year to date. Complaints have been filed against dozens of the IBCs it oversees concerning serious problems; but OBA refuses to communicate about its investigations, if the complaints have actually stirred OBA from its slumber and prompted a serious attempt at federal oversight.

Meanwhile, arms control advocates are increasingly disconcerted with OBA's imperceptibly slow movement to get the National Science Advisory Board on Biosecurity (NSABB) up and running - NSABB is the Bush administration's alleged answer to ensuring safety and good judgment in dual-use research with biological weapons. Senior administration officials announced NSABB with much fanfare in early March. But since Secretary Tommy Thompson's announcement generated a wave of publicity that gave the impression that the federal government is doing something about dual-use dangers, NSABB has remained theoretical - a paper kitten. Even its members remain unappointed.

While OBA officials fiddle with job descriptions and extend application deadlines, hundreds of millions of dollars for research on biological weapons agents continue to flow out of the National Institute of Allergy and Infectious Disease (NIAID) and other federal agencies. NIAID is an NIH agency that does not hold OBA and the NIH Guidelines in high

regard, having repeatedly funded institutions whose biosafety committees either simply do not exist or which violate federal biosafety rules in other ways.

The following paragraphs provide a brief overview of each of the ten new complaints that the Sunshine Project has filed with the NIH Office of Biotechnology Activities.

Utah State University (Logan, UT)
Utah State says that its IBC somehow managed to "approve" at least 48 research protocols before the committee was ever organized. Utah State could not produce any minutes of meetings of its IBC, except those of an emergency meeting - its first meeting ever - called after the Sunshine Project requested its IBC minutes. At its first meeting, Utah State's IBC leaders thoughtfully provided the committee members with a list of the projects that the committee had approved over a period of six and half years - before it actually existed. Utah State University thought that it was a good candidate to receive a BSL-4 National Biocontainment Laboratory grant from NIAID and has a virology institute that actively advertises its large collection of biological weapons agents and its knowledge of how to manipulate them.

The State University of New York at Stony Brook (SUNY-SB)
SUNY-SB conducts a large amount of NIH and DOD-funded biological weapons research, yet its IBC maintains atrocious records that it holds for up to a year and a half before release to the public. To top it off, SUNY-SB has decided to consider its IBC records 'informal' and 'intra-agency', allowing it to invoke New York State open records law to gut the content of its already poor IBC minutes. In addition to maintaining inadequate records, SUNY-SB's stance on records access is in direct conflict with the NIH Guidelines, which require that the documents be promptly released, that they be formal records, and that they be public (as opposed to "intra-agency").

The Salk Institute (La Jolla, CA)
The renowned Salk Institute, a major recipient of federal research money, cannot produce a single page of minutes from any meeting of its institutional biosafety committee. Salk claims that none of its work on items such as anthrax toxins, genetically-engineered viruses, and gene therapy techniques requires review by an institutional biosafety committee. Salk's moribund IBC is an interesting example of what the Bush administration calls the 'culture of responsibility' among institutional biosafety committees.

The Donald Danforth Plant Science Center (St. Louis, MO)
Like Salk, the Danforth Center is an interesting example of just how strong the biosafety "culture of responsibility" is among prestigious institutions. On its Board of Trustees, the Danforth Center counts the President of the National Academies of Science, the current or former CEOs of the Monsanto, Merck, and McDonnell Douglas Corporations, and a fistful of university presidents. The Danforth Center receives funding from NIH and USDA; but it does not have an IBC that works. It can produce minutes of only one meeting, a meeting that was called two weeks after the Sunshine Project requested Danforth's IBC minutes. At the meeting, IBC members were introduced to concepts such as what an IBC is, and what its responsibilities are - suggesting that the meeting was, in fact, the only IBC meeting that has ever taken place. Danforth's IBC membership does not comply with the NIH Guidelines and its IBC does not meet to review the safety of biotechnology research at the institute.

Carnegie Mellon University (Pittsburgh, PA)
Carnegie Mellon's IBC has, for at least two and a half years, been in an ongoing state of sporadically trying to organize itself and to first identify all of the biotechnology research on campus that it needs to oversee. In 2002, the nascent Carnegie Mellon IBC deferred approval for a whopping 11 research projects, saying that they needed to be addressed at the IBC's next meeting. The 11 projects were never heard from again. At the next meeting, which occurred more than a year later, there is no mention of them. The Sunshine Project asked Carnegie Mellon what happened to these projects. The University said it would respond; but in the end it didn't. It appears that at least some of the projects were "approved" without actually being reviewed.

Medical College of Wisconsin (Milwaukee, WI)
The Medical College of Wisconsin (MCW) has more than 4,000 employees, 1200 students, and receives almost $120 million in annual research grants, many of which come from NIH. Its research includes a wide variety of biotechnology studies and work with the biological weapons agents plague and botulinum toxin. MCW cannot produce any meeting minutes because it says its Institutional Biosafety Committee has never met.

Medical College of Georgia (Augusta, GA)
With 750 faculty, over 2000 students, and $169 million in external funding, the Medical College of Georgia (MCG) also dips into NIH's coffers for biotechnology research grants. Unlike MCW, MCG can produce some IBC minutes;

but the problem is that its IBC doesn't do its job of reviewing research projects to ensure safety - not even for BSL-3 projects. MCG says, "Our IBC does not meet as a committee to review protocols". In violation of the NIH Guidelines, the MCG IBC has effectively abdicated responsibility for biosafety and instead devotes its meetings to discussion of how biosafety paperwork can be made "very user-friendly", expedited and simplified.

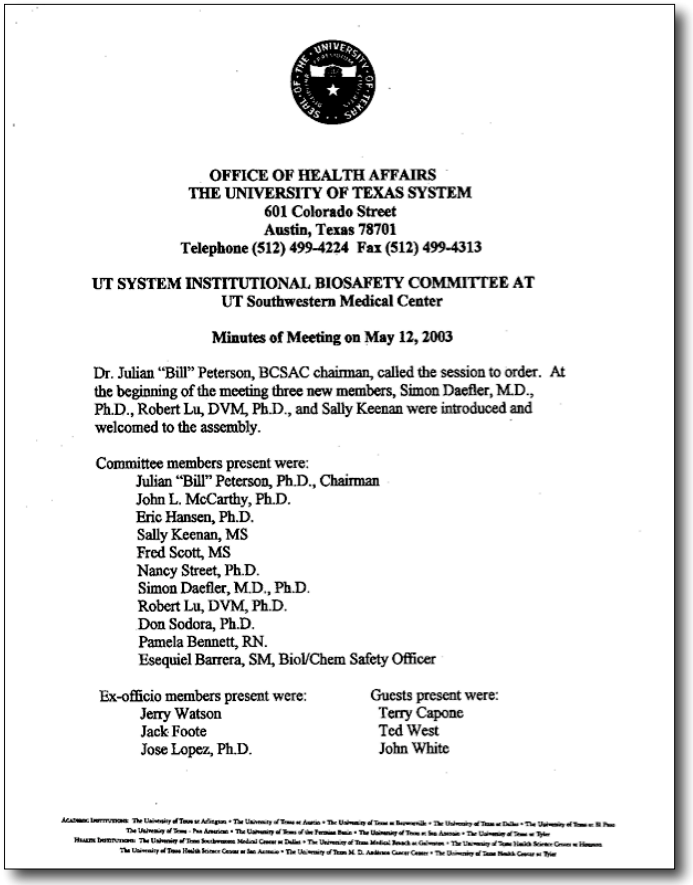
Washington University (St. Louis, MO)
The Sunshine Project first complained to OBA about Washington's refusal to properly release its IBC records in March of this year. In one of its very few public actions related to the Sunshine Project's complaints, OBA did direct Washington University and other IBCs to provide copies of their IBC minutes. But Washington University, which has hundreds of ongoing NIH-funded projects, is effectively refusing to obey an explicit order from OBA. (Other institutions, most notably Iowa State University, are also reluctant to comply.) While Washington University openly defies OBA and the NIH Guidelines, NIH research grants continue to flow into its coffers, thus revealing how extraordinarily weak US government oversight is of laboratory biosafety.

University of Kansas Medical Center (Kansas City, KS)
The University of Kansas Medical Center (UKMC) refuses to release its IBC records unless requesters explicitly agree to a set of terms and conditions that are posted on its website. UKMC's position violates the NIH Guidelines, which require release of IBC records to the public upon request.

University of Nebraska Medical Center (Omaha, NB)
The University of Nebraska Medical Center (UNMC), which entertains notions of building a biosafety level four laboratory, cannot produce a single page of minutes from a meeting of its institutional biosafety committee. After six months of playing e-mail footsie, Nebraska finally decided that it could come up with documents from alleged "electronic meetings" of its IBC. Curiously, the records of these "electronic meetings" are not available in electronic format. Having ignored the requirements of the NIH Guidelines and delayed its response, Nebraska has now invoked its state open records law and says that it can only release the paper version of its electronic records in return for nearly $100, a prohibitively high cost for almost all public requesters.

ANNEX 2: HALL OF SHAME

In this annex, the Sunshine Project presents "awards" to some of the most troubling responses to the IBC survey. The titles may be a bit light-hearted, but they can't mask the serious problems evidenced in the documents reproduced here.



OFFICE OF HEALTH AFFAIRS
THE UNIVERSITY OF TEXAS SYSTEM
601 Colorado Street
Austin, Texas 78701
Telephone (512) 499-4224 Fax (512) 499-4313

UT SYSTEM INSTITUTIONAL BIOSAFETY COMMITTEE AT UT Southwestern Medical Center

Minutes of Meeting on May 12, 2003

Dr. Julian "Bill" Peterson, BCSAC chairman, called the session to order. At the beginning of the meeting three new members, Simon Daefler, M.D., Ph.D., Robert Lu, DVM, Ph.D., and Sally Keenan were introduced and welcomed to the assembly.

Committee members present were:
Julian "Bill" Peterson, Ph.D., Chairman
John L. McCarthy, Ph.D.
Eric Hansen, Ph.D.
Sally Keenan, MS
Fred Scott, MS
Nancy Street, Ph.D.
Simon Daefler, M.D., Ph.D.
Robert Lu, DVM, Ph.D.
Don Sodora, Ph.D.
Pamela Bennett, RN.
Esequiel Barrera, SM, Biol/Chem Safety Officer

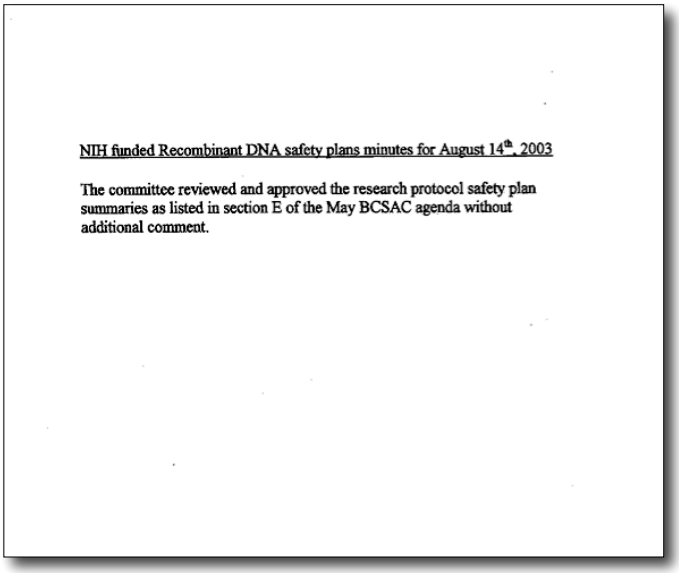
Ex-officio members present were:
Jerry Watson
Jack Foote
Jose Lopez, Ph.D.

Guests present were:
Terry Capone
Ted West
John White

Most Blatant Evasion of Public Accountability

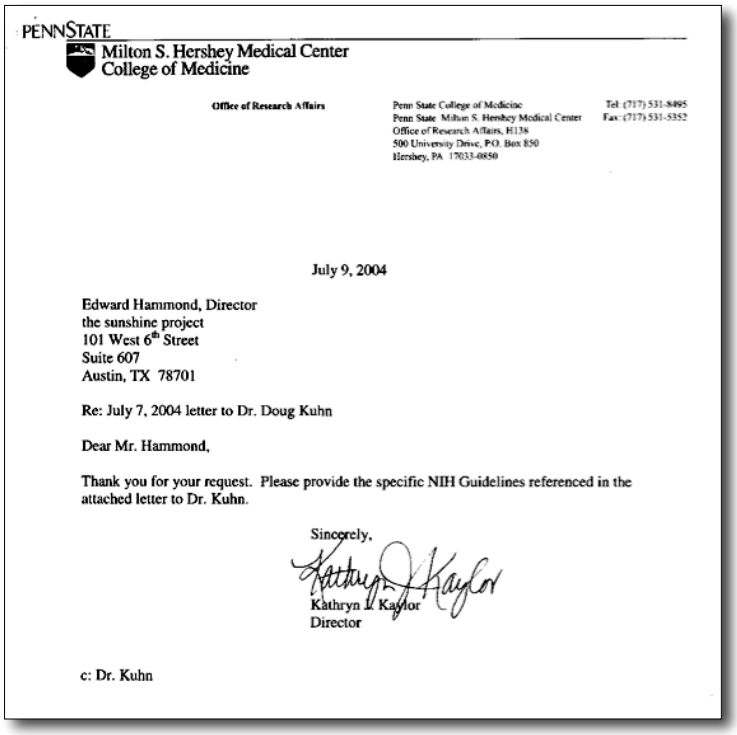
The University of Texas Southwestern
Dallas, Texas

To avoid disclosure of its IBC activity, UT Southwestern created a farce committee whose documentation is hidden in "safety plan summaries". The entire two page minutes of a UT Southwestern IBC meeting are reproduced here.



NIH funded Recombinant DNA safety plans minutes for August 14th, 2003

The committee reviewed and approved the research protocol safety plan summaries as listed in section E of the May BCSAC agenda without additional comment.



PENNSTATE
Milton S. Hershey Medical Center
College of Medicine

Office of Research Affairs

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Tel: (717) 531-8495
Fax: (717) 531-5352

July 9, 2004

Edward Hammond, Director
the sunshine project
101 West 6th Street
Suite 607
Austin, TX 78701

Re: July 7, 2004 letter to Dr. Doug Kuhn

Dear Mr. Hammond,

Thank you for your request. Please provide the specific NIH Guidelines referenced in the attached letter to Dr. Kuhn.

Sincerely,

Kathryn J. Kaylor
Director

c: Dr. Kuhn

Most Knowledgeable About the NIH Guidelines

Pennsylvania State University Medical College
Hershey, Pennsylvania

At left is PSUMC's reply to the Sunshine Project's third request for its IBC minutes. It ignored the first two requests. (PSUMC later provided redacted minutes.)

Least Competently Concealed Classified Biological Research Program

Southwest Foundation for Biomedical Research

San Antonio, Texas

Southwest Regional Primate Research Center
and
Southwest Foundation for Biomedical Research

Department of Virology and Immunology
Robert E. Lanford, Ph.D.
Scientist

June 4, 2004

Edward Hammond
The Sunshine Project
101 West 6th Street Suite 607
Austin TX, 78701

1 This is in response to your letter dated May 28,2004. We acknowledge receipt of your request for minutes of our IBC meetings from June 1, 2003 to May 28, 2004. Please send all requests by registered mail, as we have no way of verifying the authenticity of a Fax that comes to a common Fax machine within our institute.

2 3

4 We have reviewed the requested records. No new proposals were submitted during the time frame of your request. We are a small institute that is not heavily invested in recombinant DNA research and some years pass without new proposals.

5

Sincerely,

Robert E. Lanford, Ph.D.
Chair, Recombinant DNA Committee

1 "... send all requests by registered mail..."

Registered mail (not to be confused with certified mail) is an unusual and expensive method of sending letters, costing between $8 and $30 to send a single sheet of paper. Registered mail is the US Postal Service's "high security" option. Registered mail is kept under lock and key and is the only way that US government information that is classified "secret" may be sent through the US mail.

2 "... verifying the authenticity ..."

The minutes of meetings of IBCs must be made available to any member of the public upon request. There is no need to verify any request, because it must be honored no matter who the requester is. The insistence on verification is that of an institution with secrets to keep.

3 "... a common Fax machine ..."

The distinction that SFBR is making here is between a regular ("common") fax that is on an open communications infrastructure versus a machine on a private network, which permits classified information to be sent to and from SFBR's patrons.

4 "... We have reviewed the requested records ..."

SFBR clearly states that the committee has met and has produced minutes that are responsive to the Sunshine Project's request. Yet SFBR does not provide them.

5 "... some years pass without new proposals ..."

Having acknolwedged that its IBC has met and has produced responsive records, SFBR then muddies the water by talking ambiguously about new proposals.

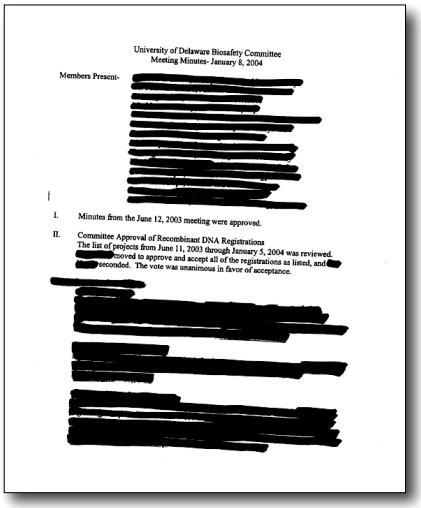
In the end, SFBR produced a single page that consists of the titles and approved dates of 12 projects. It refused to elaborate on the IBC meetings and minutes.

Most Likely to Wear a Pocket Protector

University of Delaware

Newark, Delaware

Master of the magic marker, the University of Delaware presented the following five pages of IBC minutes in alleged fulfillment of the public access provisions of the NIH Guidelines.

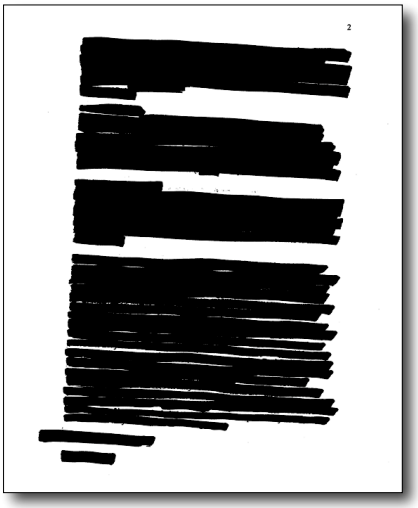


University of Delaware Biosafety Committee
Meeting Minutes- January 8, 2004

Members Present-

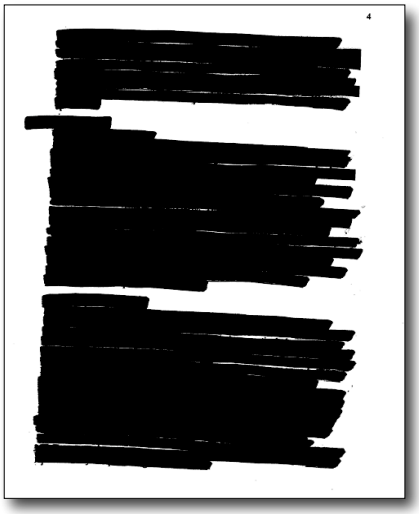
I. Minutes from the June 12, 2003 meeting were approved.

II. Committee Approval of Recombinant DNA Registrations
The list of projects from June 11, 2003 through January 5, 2004 was reviewed. [redacted] moved to approve and accept all of the registrations as listed, and [redacted] seconded. The vote was unanimous in favor of acceptance.

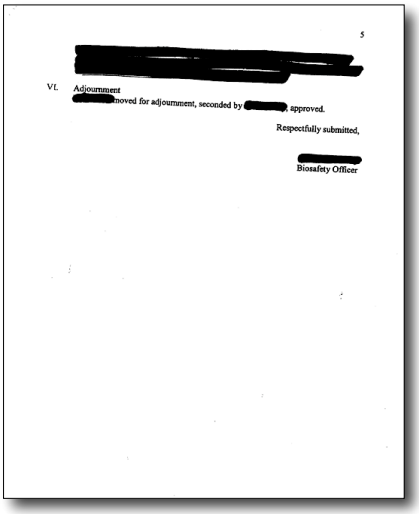


2

3



4

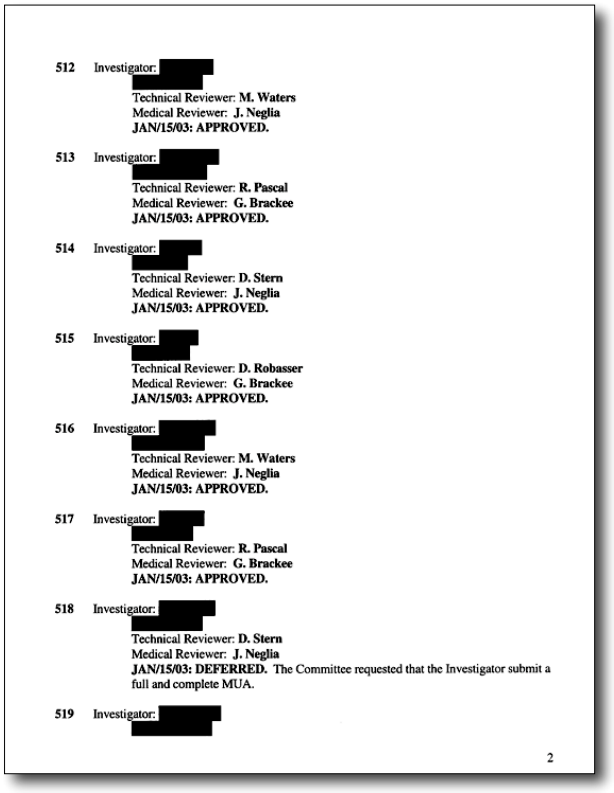


5

VI. Adjournment
[redacted] moved for adjournment, seconded by [redacted], approved.

Respectfully submitted,

[redacted]
Biosafety Officer



512 Investigator: [redacted]
Technical Reviewer: **M. Waters**
Medical Reviewer: **J. Neglia**
JAN/15/03: APPROVED.

513 Investigator: [redacted]
Technical Reviewer: **R. Pascal**
Medical Reviewer: **G. Brackee**
JAN/15/03: APPROVED.

514 Investigator: [redacted]
Technical Reviewer: **D. Stern**
Medical Reviewer: **J. Neglia**
JAN/15/03: APPROVED.

515 Investigator: [redacted]
Technical Reviewer: **D. Robasser**
Medical Reviewer: **G. Brackee**
JAN/15/03: APPROVED.

516 Investigator: [redacted]
Technical Reviewer: **M. Waters**
Medical Reviewer: **J. Neglia**
JAN/15/03: APPROVED.

517 Investigator: [redacted]
Technical Reviewer: **R. Pascal**
Medical Reviewer: **G. Brackee**
JAN/15/03: APPROVED.

518 Investigator: [redacted]
Technical Reviewer: **D. Stern**
Medical Reviewer: **J. Neglia**
JAN/15/03: DEFERRED. The Committee requested that the Investigator submit a full and complete MUA.

519 Investigator: [redacted]

2

Most Economical Use of Microsoft Word

Princeton University
Princeton, New Jersey

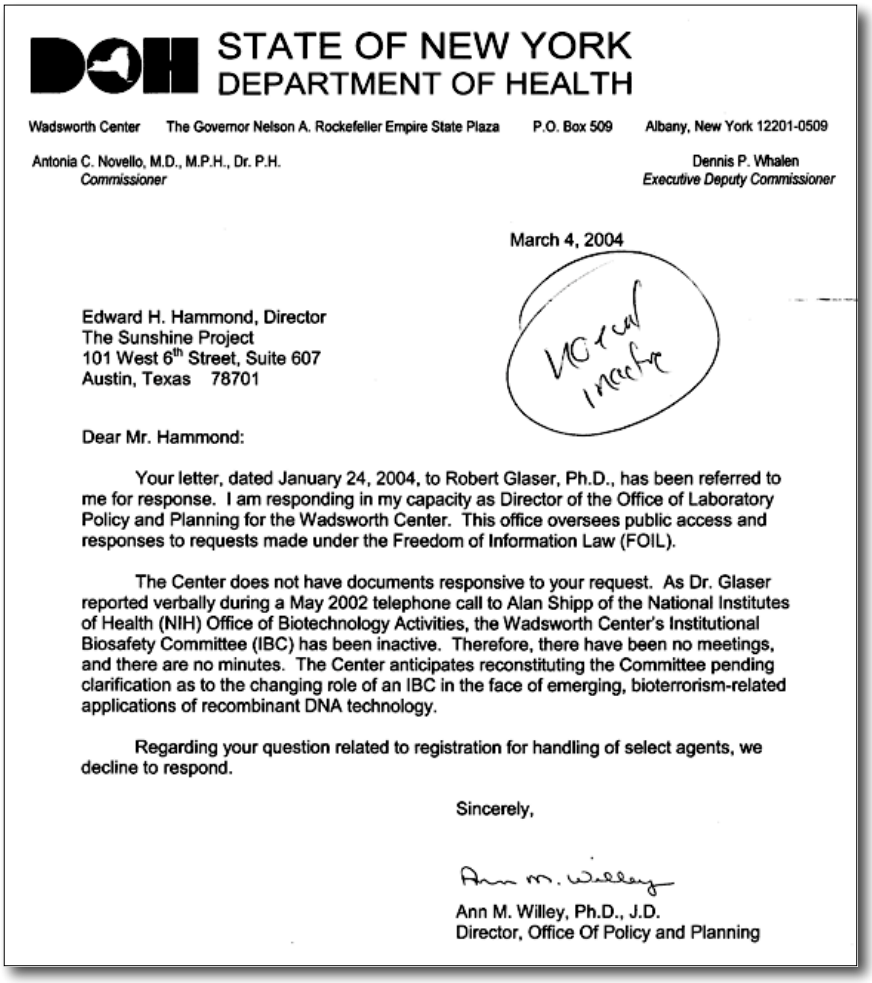
A typical page from Princeton's useless IBC minutes is reproduced at left. This is the extent of the information that Princeton provides to the public about IBC review of individual projects. The University of Vermont takes a similar approach.

Most Remarkable Biodefense Chutzpah

NY State Department of Health
Wadsworth Center
Albany, NY

The Wadsworth Center does not maintain an institutional biosafety committee and does not tell the public if it handles select agents. (The truth: Yes, it does.)

Wadsworth nevertheless thinks that it is an appropriate candidate to receive federal funding to build a massive BSL-4 national biocontainment laboratory.



STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

March 4, 2004

Edward H. Hammond, Director
The Sunshine Project
101 West 6th Street, Suite 607
Austin, Texas 78701

Dear Mr. Hammond:

Your letter, dated January 24, 2004, to Robert Glaser, Ph.D., has been referred to me for response. I am responding in my capacity as Director of the Office of Laboratory Policy and Planning for the Wadsworth Center. This office oversees public access and responses to requests made under the Freedom of Information Law (FOIL).

The Center does not have documents responsive to your request. As Dr. Glaser reported verbally during a May 2002 telephone call to Alan Shipp of the National Institutes of Health (NIH) Office of Biotechnology Activities, the Wadsworth Center's Institutional Biosafety Committee (IBC) has been inactive. Therefore, there have been no meetings, and there are no minutes. The Center anticipates reconstituting the Committee pending clarification as to the changing role of an IBC in the face of emerging, bioterrorism-related applications of recombinant DNA technology.

Regarding your question related to registration for handling of select agents, we decline to respond.

Sincerely,

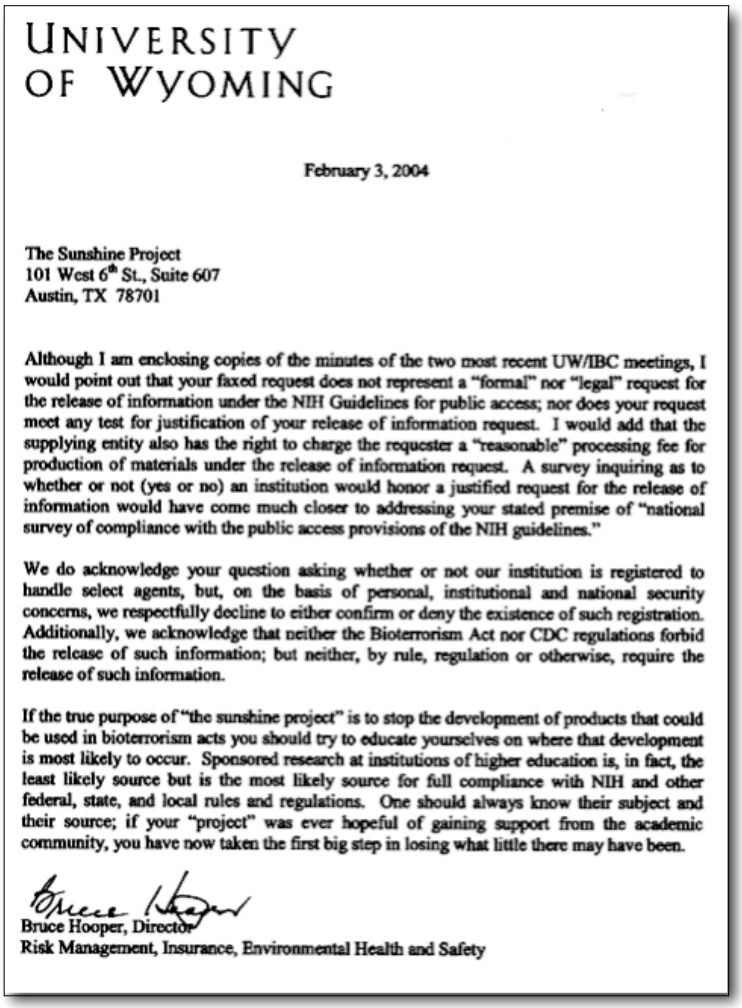
Ann M. Willey, Ph.D., J.D.
Director, Office Of Policy and Planning

Most Contemptuous of the Citizenry

University of Wyoming
Laramie, Wyoming

The cover letter for Wyoming's IBC minutes is reproduced at right.

In its second paragraph, Wyoming copied language developed by the University of New Hampshire to explain its refusal to answer the survey question concerning select agents. Remarkably, none of the institutions that used New Hampshire's sentence paused to reflect that they were incompetent to make national security determinations and that the survey did not ask about individuals registered to handle select agents.



UNIVERSITY
OF WYOMING

February 3, 2004

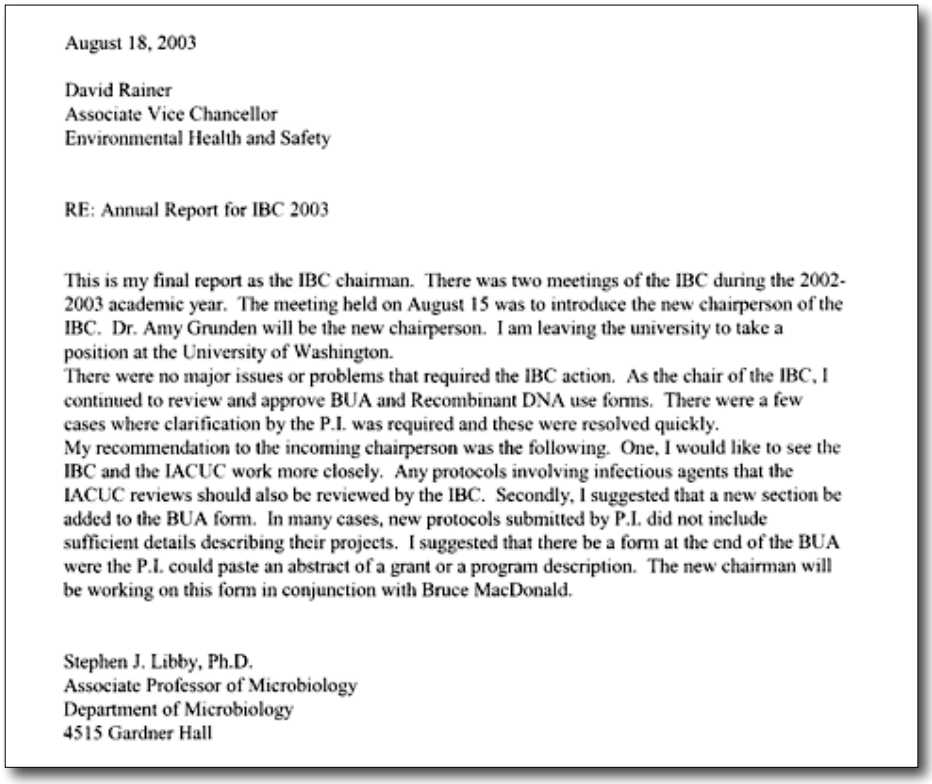
The Sunshine Project
101 West 6th St., Suite 607
Austin, TX 78701

Although I am enclosing copies of the minutes of the two most recent UW/IBC meetings, I would point out that your faxed request does not represent a "formal" nor "legal" request for the release of information under the NIH Guidelines for public access; nor does your request meet any test for justification of your release of information request. I would add that the supplying entity also has the right to charge the requester a "reasonable" processing fee for production of materials under the release of information request. A survey inquiring as to whether or not (yes or no) an institution would honor a justified request for the release of information would have come much closer to addressing your stated premise of "national survey of compliance with the public access provisions of the NIH guidelines."

We do acknowledge your question asking whether or not our institution is registered to handle select agents, but, on the basis of personal, institutional and national security concerns, we respectfully decline to either confirm or deny the existence of such registration. Additionally, we acknowledge that neither the Bioterrorism Act nor CDC regulations forbid the release of such information; but neither, by rule, regulation or otherwise, require the release of such information.

If the true purpose of "the sunshine project" is to stop the development of products that could be used in bioterrorism acts you should try to educate yourselves on where that development is most likely to occur. Sponsored research at institutions of higher education is, in fact, the least likely source but is the most likely source for full compliance with NIH and other federal, state, and local rules and regulations. One should always know their subject and their source; if your "project" was ever hopeful of gaining support from the academic community, you have now taken the first big step in losing what little there may have been.

Bruce Hooper, Director
Risk Management, Insurance, Environmental Health and Safety



August 18, 2003

David Rainer
Associate Vice Chancellor
Environmental Health and Safety

RE: Annual Report for IBC 2003

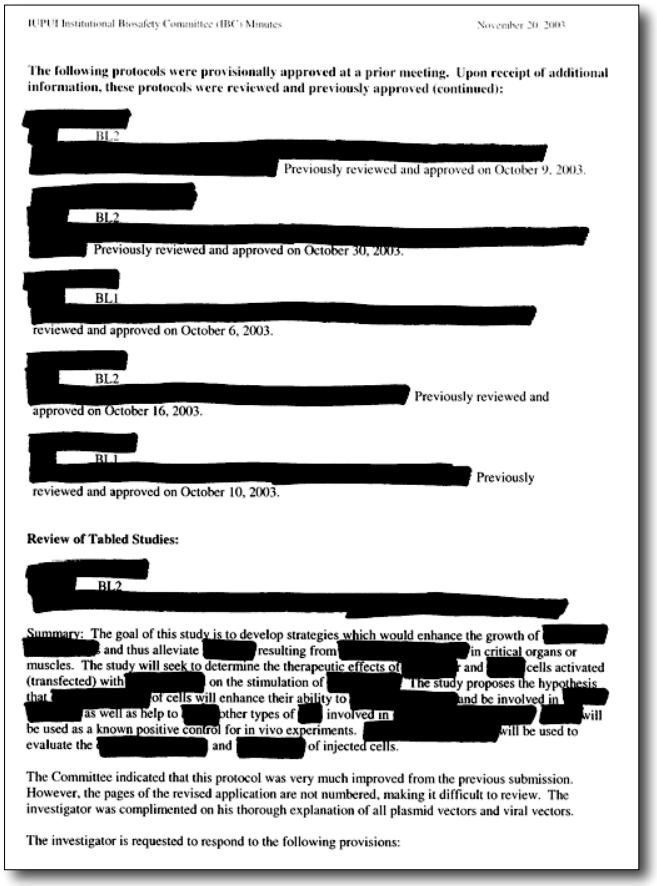
This is my final report as the IBC chairman. There was two meetings of the IBC during the 2002-2003 academic year. The meeting held on August 15 was to introduce the new chairperson of the IBC. Dr. Amy Grunden will be the new chairperson. I am leaving the university to take a position at the University of Washington.
There were no major issues or problems that required the IBC action. As the chair of the IBC, I continued to review and approve BUA and Recombinant DNA use forms. There were a few cases where clarification by the P.I. was required and these were resolved quickly.
My recommendation to the incoming chairperson was the following. One, I would like to see the IBC and the IACUC work more closely. Any protocols involving infectious agents that the IACUC reviews should also be reviewed by the IBC. Secondly, I suggested that a new section be added to the BUA form. In many cases, new protocols submitted by P.I. did not include sufficient details describing their projects. I suggested that there be a form at the end of the BUA were the P.I. could paste an abstract of a grant or a program description. The new chairman will be working on this form in conjunction with Bruce MacDonald.

Stephen J. Libby, Ph.D.
Associate Professor of Microbiology
Department of Microbiology
4515 Gardner Hall

Most Dubious After-the-Fact Manufacture of Records

North Carolina State University
Raleigh, North Carolina

The partial page printout of an e-mail reproduced at left constitutes the entire substantive portion of NC State's reply. NC State was not the only institution to create IBC minutes in response to the survey.



IUPUI Institutional Biosafety Committee (IBC) Minutes November 20, 2003

The following protocols were provisionally approved at a prior meeting. Upon receipt of additional information, these protocols were reviewed and previously approved (continued):

[redacted] BL2 [redacted] Previously reviewed and approved on October 9, 2003.

[redacted] BL2 [redacted] Previously reviewed and approved on October 30, 2003.

[redacted] BL1 [redacted] reviewed and approved on October 6, 2003.

[redacted] BL2 [redacted] Previously reviewed and approved on October 16, 2003.

[redacted] BL1 [redacted] Previously reviewed and approved on October 10, 2003.

Review of Tabled Studies:

[redacted] BL2 [redacted]

Summary: The goal of this study is to develop strategies which would enhance the growth of [redacted] and thus alleviate [redacted] resulting from [redacted] in critical organs or muscles. The study will seek to determine the therapeutic effects of [redacted] and [redacted] cells activated (transfected) with [redacted] on the stimulation of [redacted]. The study proposes the hypothesis that [redacted] of cells will enhance their ability to [redacted] and be involved in [redacted] as well as help to [redacted] other types of [redacted] involved in [redacted] will be used as a known positive control for in vivo experiments. [redacted] will be used to evaluate the [redacted] and [redacted] of injected cells.

The Committee indicated that this protocol was very much improved from the previous submission. However, the pages of the revised application are not numbered, making it difficult to review. The investigator was complimented on his thorough explanation of all plasmid vectors and viral vectors.

The investigator is requested to respond to the following provisions:

Dishonorable Mention: Pocket Protector Category

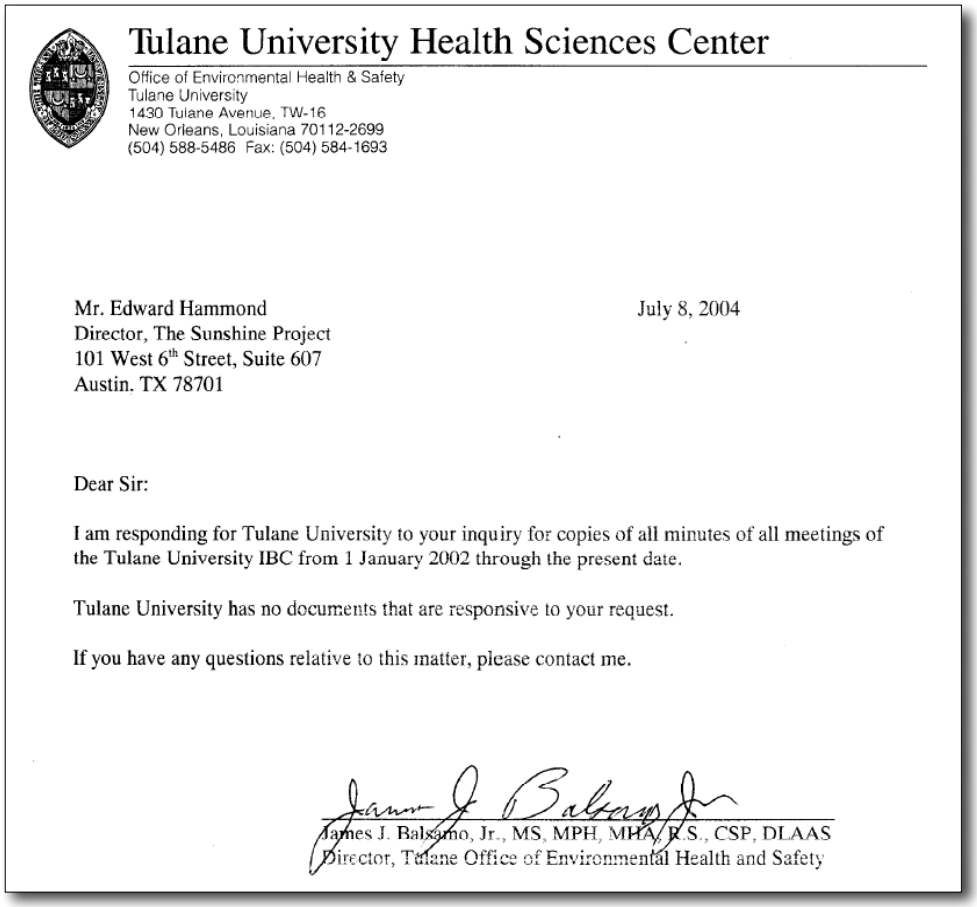
Indiana University
Indianapolis, Indiana

A page from Indiana University's heavily-redacted IBC minutes of 20 November 2003. With flagrant disregard for the NIH Guidelines, Indiana cited a state law and redacted *"information concerning research", "expressions of opinion", "advisory or deliberative material"*, and information *"communicated for the purpose of decision making"*. The redactions defeat the core purposes of the public access provisions of the NIH Guidelines and make the minutes substantively unintelligible.

Most Frightened Monkeys

Tulane University
New Orleans and Covington, Louisiana

Tulane's whopping collection of 5000 research primates can't take much solace in Tulane's dysfunctional IBC, much less humans. Tulane refused to reply to the survey at all, until it was sent certified mail and correspondence was copied to the National Institutes of Health.



Tulane University Health Sciences Center

Office of Environmental Health & Safety
Tulane University
1430 Tulane Avenue, TW-16
New Orleans, Louisiana 70112-2699
(504) 588-5486 Fax: (504) 584-1693

Mr. Edward Hammond
Director, The Sunshine Project
101 West 6th Street, Suite 607
Austin, TX 78701

July 8, 2004

Dear Sir:

I am responding for Tulane University to your inquiry for copies of all minutes of all meetings of the Tulane University IBC from 1 January 2002 through the present date.

Tulane University has no documents that are responsive to your request.

If you have any questions relative to this matter, please contact me.

James J. Balsamo, Jr., MS, MPH, MHA, R.S., CSP, DLAAS
Director, Tulane Office of Environmental Health and Safety

Best Cabin Boy to the Biotechnology Industry

University of Hawaii
Manoa, Hawaii

According to minutes provided by the University of Hawaii, it's IBC operates as a service provider for Monsanto company trials of genetically-modified crops. The "minutes" of one Hawaii IBC meeting, in their entirety, are at right. See Biosafety Bites for more detail.

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

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.

Biggest (Known) IBC Mess at a Spooky Department of Defense Contractor

Southern Research Institute
Frederick, Maryland

The IBC minutes of the defense-contracting facility that sent live anthrax to Children's Hospital in Oakland, California. No information is provided about the protocols allegedly reviewed, and no further comment is necessary.

Southern Research Institute Frederick
Institutional Biosafety Committee
Meeting Minutes
26 November 2003

1. Call to Order

Chairman, [redacted] called the meeting to order at 205 PM.

2. Attendance

Four of the five committee members were in attendance:

[redacted] Chairman
[redacted] member
[redacted] Animal Containment Principles Expert
[redacted] Outside community member

[redacted] (Biological Safety Officer), [redacted] (member) and [redacted] administrator) no longer are employees of Southern Research. [redacted] (lab member) had a previous engagement.

3. Review of Activities

In 2003 we reviewed five proposals.

4. Biological Safety Officer

Since [redacted] has left our IBC currently does not have a BSO, which is required on this committee. [redacted] has stated that she wishes to fuse the Frederick and Alabama IBCs into a single committee in the near future. As such, we will wait for her recommendation as to whether she will fuse the IBCs, serve as our BSO, or whether we can appoint a BSO ourselves. We will require action on this item by the spring since our annual report to the NIH is due at that time. Without a BSO on the committee we are noncompliant with regards to our membership.

5. Outside Member

We still need a second outside committee member in order for our IBC to be compliant with regards to our membership. Dr. [redacted] suggested that we might

be able to acquire one at Hood College. We will wait until [redacted] decides the fate of our committee before we pursue this further.

6. Protocols Under Review

There are no proposals currently under review.

7. Other Business

Outside member [redacted] will receive $50 for the previous protocol reviewed and $150 for attending today's meeting. A check will be prepared this month. We all thank [redacted] for his help.

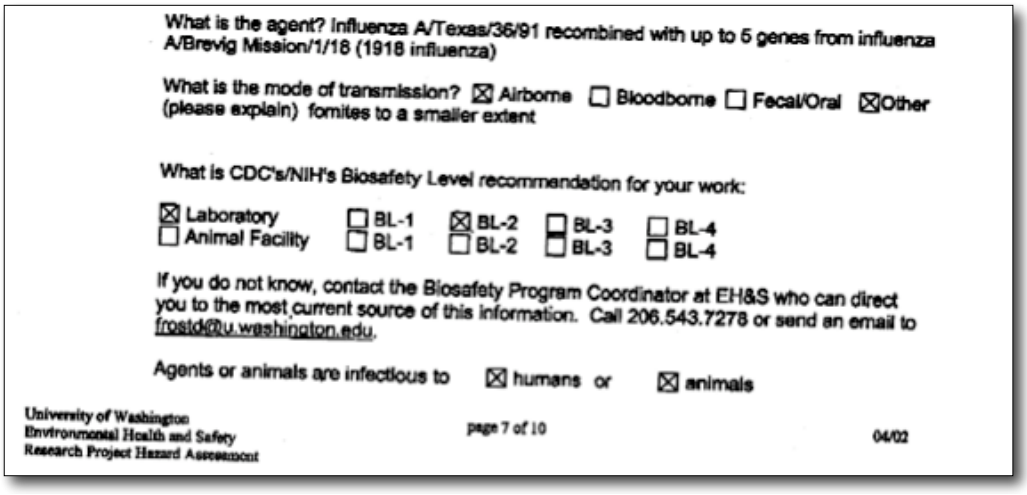
8. Adjournment

New protocols to review and the next IBC meeting schedule will be arranged via e-mail.

Most Embarrassing Moment for Biosafety "Regulators"

courtesy of the

University of Washington
Seattle, WA



What is the agent? Influenza A/Texas/36/91 recombined with up to 5 genes from influenza A/Brevig Mission/1/18 (1918 influenza)

What is the mode of transmission? ☒ Airborne ☐ Bloodborne ☐ Fecal/Oral ☒ Other (please explain) fomites to a smaller extent

What is CDC's/NIH's Biosafety Level recommendation for your work:

☒ Laboratory	☐ BL-1	☒ BL-2	☐ BL-3	☐ BL-4
☐ Animal Facility	☐ BL-1	☐ BL-2	☐ BL-3	☐ BL-4

If you do not know, contact the Biosafety Program Coordinator at EH&S who can direct you to the most current source of this information. Call 206.543.7278 or send an email to frosld@u.washington.edu.

Agents or animals are infectious to ☒ humans or ☒ animals

University of Washington
Environmental Health and Safety
Research Project Hazard Assessment

page 7 of 10

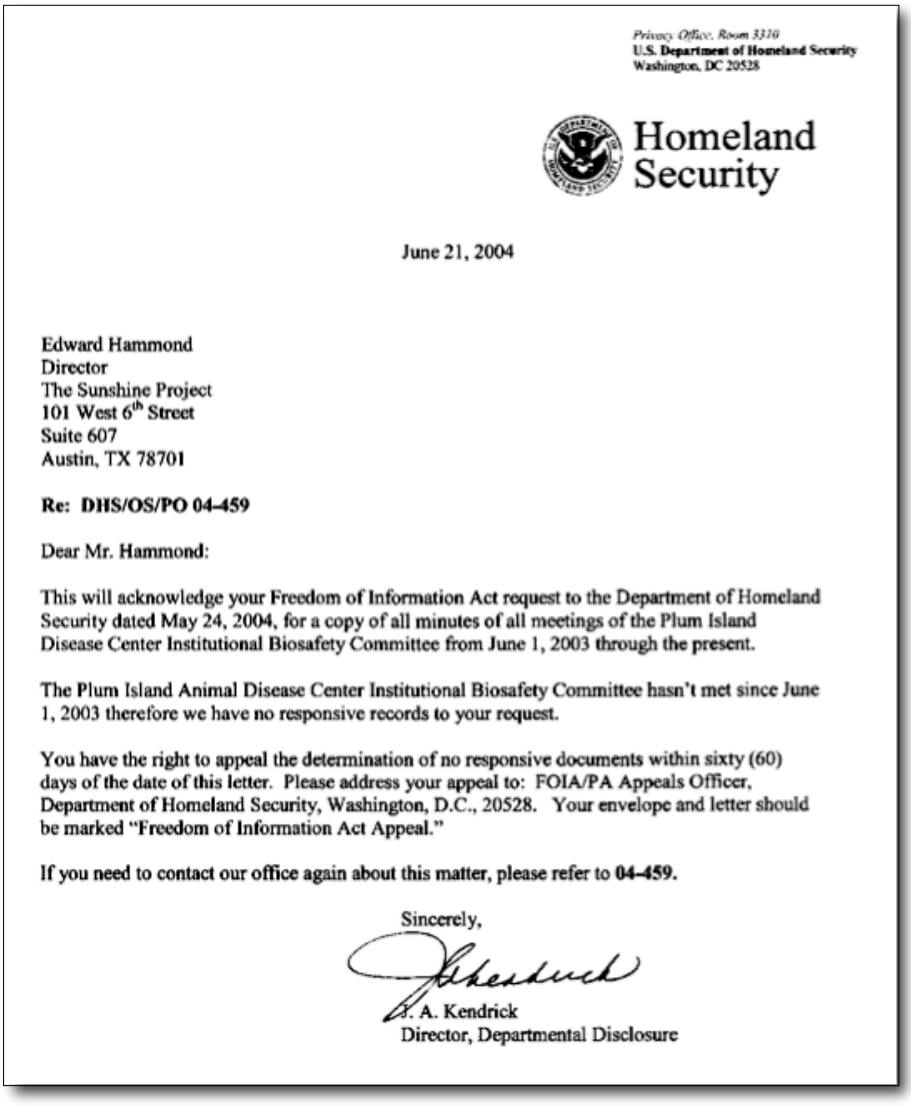
04/02

Of course, because there are no comprehensive laboratory safety regulations, the US does not have federal lab safety "regulators". Instead it has "guideliners" and manual writers, whose products are optional reading material for laboratories. Exactly how permissive and flat-footed the US lab safety system is can be seen above: Four years after recreation of the 1918 "Spanish" Flu began elsewhere, the University of Washington (starting 1918 flu experiments of its own) was correct to conclude that federal guidelines still classify recombinant influenza virus that is almost entirely composed of 1918 genes (including the virulence-related genes) as requiring only modest BSL-2 containment. As of September 2004, the government is developing optional advice to labs like the University of Washington's, which they may choose to accept or ignore, as they recreate old pandemic flu and, perhaps, create new ones, both of which, by accident or design, might literally kill millions if accidentally released.

Least Likely to Instill Confidence Among Citizens

Department of Homeland Security
Washington, DC and Plum Island, New York

The Department of Homeland Security's reply to the survey for its Plum Island Animal Disease Center (formerly operated by USDA). See Biosafety Bites for more information.



Privacy Office, Room 3310
U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

June 21, 2004

Edward Hammond
Director
The Sunshine Project
101 West 6th Street
Suite 607
Austin, TX 78701

Re: DHS/OS/PO 04-459

Dear Mr. Hammond:

This will acknowledge your Freedom of Information Act request to the Department of Homeland Security dated May 24, 2004, for a copy of all minutes of all meetings of the Plum Island Disease Center Institutional Biosafety Committee from June 1, 2003 through the present.

The Plum Island Animal Disease Center Institutional Biosafety Committee hasn't met since June 1, 2003 therefore we have no responsive records to your request.

You have the right to appeal the determination of no responsive documents within sixty (60) days of the date of this letter. Please address your appeal to: FOIA/PA Appeals Officer, Department of Homeland Security, Washington, D.C., 20528. Your envelope and letter should be marked "Freedom of Information Act Appeal."

If you need to contact our office again about this matter, please refer to **04-459.**

Sincerely,

J. A. Kendrick
Director, Departmental Disclosure