

INDIANA UNIVERSITY



April 28, 2006

Edward H. Hammond
Director
the sunshine project
P.O. Box 41967
Austin, TX 78704

OFFICE OF
UNIVERSITY COUNSEL

Re: Request for Biosafety Committee meeting minutes

In response to your letter of March 15, 2006, please find enclosed copies of the minutes from the meetings since May 1, 2003 of the Indiana University—Bloomington Institutional Biosafety Committee (IBC). We have redacted these minutes in accordance with the terms of Indiana's Access to Public Records Act ("APRA"), Indiana Code 5-14-3 et seq.

The APRA prohibits the University from disclosing "information concerning research" and "records containing trade secrets" unless disclosure is specifically required by a federal or state statute or ordered by a court under the rules of discovery. IC 5-14-3-3(a)(4), (6). The APRA further provides for the nondisclosure of:

- The work product of an attorney representing a public agency (IC 5-14-3-4(b)(2);
- Records that are intra-agency or interagency advisory or deliberative material ... that are expressions of opinion or are of a speculative nature, and that are communicated for the purpose of decision making (IC 5-14-3-4(b)(6);
- Administrative or technical information that would jeopardize a recordkeeping or security system (IC 5-14-3-4(b)(10); and
- A record or a part of a record, the public disclosure of which would have a reasonable likelihood of threatening public safety by exposing a vulnerability to terrorist attack (IC 5-14-3-4(b)(19).

These redactions are consistent with the NIH Guidelines (which do not constitute a federal statute) as well as state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Beth Cate".

Beth Cate
Associate University Counsel

BEC:acw

Encl.

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INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

SEPTEMBER 22, 2005

Present:

[REDACTED]
Beth Reeves, [REDACTED]

Absent:

CONSIDERATION OF THE MAY 6, 2005 MINUTES:

The minutes for the May 6, 2005 were approved.

ANNOUNCEMENTS:

1. MaBion Conference IUPUI August 1&2, 2005 discussed by [REDACTED] Jim Klenner President, PowerPoint presentations available to the members. The term Dual Use was discussed, it's meaning and application to fundamental research.
2. ABSA conference in Vancouver Canada October 23-26, 2005 [REDACTED] and Beth Reeves will be attending.
3. Biosafety Manual; Jim Klenner has granted permission for us to use the IUPUI Biosafety Manual as a template for the Bloomington Biosafety Manual. After initial modifications are made, a draft for review will be sent via email to the members.
4. Minors in the lab and Visitors Policy; brief discussion followed concerning safety training documentation for short time visitors.

OLD BUSINESS:

1. [REDACTED] contacted Laura Schreiber for protocols dealing with animal remains. She is developing one and will send it to Chris when completed.
2. Brief discussion reaffirming [REDACTED] as the Co-Chair of the Human Tissues and Fluids subcommittee and presentation of the updated BBPECP.
3. [REDACTED] facility in [REDACTED] will be online shortly, materials for programming the locks is in process.

New Business:

1. 05-009 Principal Investigator; [REDACTED], Project Title; [REDACTED] Approved 9/22/05.
2. 05-017 Principal Investigator; [REDACTED] Project Title; [REDACTED] Approved 9/22/05.

3. 05-016 Principal Investigator: [REDACTED], Project Title; [REDACTED]
[REDACTED] Approved pending documentation of
IRB approval if needed, lab inspection and where the sample will be stored,
what will be done with it. 9/22/05.

*Covered
by IRB
in Italy.*

[REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

MAY 6, 2005

Present:

[REDACTED] Beth Reeves, [REDACTED]

Absent:

CONSIDERATION OF THE DECEMBER 15, 2004 MINUTES:

The minutes for the December 15, 2004 meeting were approved with the change of Andrew Feig as present, not absent, and correct the spelling of *Plesiomonas*.

ANNOUNCEMENTS:

1. Export Controls

[REDACTED] led the discussion concerning the Export Control Administration Regulations. The University of Santa Clara, CA attempted to export the Yellow Fever virus to Australia and was stopped at the border, resulting in one million dollar fine to the university.

Discussion and brief explanation of the Commerce Control List and how this affects the members of the IBC. Also [REDACTED] mentioned the area of deemed exports, list of exemptions, proprietary vs. publically available information. Ann Gellis is taking the lead on this subject, but will need the cooperation and assistance of the departments in assessing what is and isn't present in the labs. First step is to schedule two meetings led by Ann Gellis to inform the departmental heads of these regulations.

2. [REDACTED]

[REDACTED] reports on the progress of [REDACTED] At this point he is waiting on the cabinets to be installed. Discussion concerning the commissioning of the [REDACTED] facility and the availability of funds leftover for this. Security software and hardware is being installed and Beth will have control over who has access to the facilities once the software is installed.

[REDACTED] led the discussion concerning space for the [REDACTED] facility with regard to the new

██████████ facility vs. using the facilities in ██████████. Due to structural problems with the facilities in the new ██████████, ██████████ will probably be the best choice for consideration at this time. The Biology department along with the IMBI will be discussing whether or not ██████████ work is an area they want to pursue.

Discussion followed concerning preparation, time and cost for ██████████, and the possibility of using ██████████ for animal research as well. More information from the USDA is needed to clarify what would need to be done to meet their specifications.

Discussion followed, led by ██████████, the next issue the Biology department needs to decide on is do we, as a department, want to pursue ██████████ work. Beth Raff will need to address this, and the Laboratory Safety Committee.

██████████ said that this would involve Rudy Raff, the IMBI, as well as Biology. Since the ██████████ is actually an IMBI facility. ██████████ also mentioned that the facilities management committee would need to be involved.

3. NIH Letter

██████████ led the discussion concerning the Sunshine Company and their response to the redacted minutes. Mike Jenson said that they Sunshine Group is more focused on the minutes from IUPUI than Bloomington's. ██████████

4. Frequency of IBC meetings

Discussion followed concerning the frequency of the IBC meetings. Meetings are held three times a year, Spring, (during finals week), Fall, (second week of first semester), and Winter, (week before Christmas break). The meetings were scheduled to correspond with NIH submission deadlines. If anyone feels that the committee should meet more frequently, it is open for consideration. It was suggested that after the Laboratory Research compliance Committee meetings are held, that Beth prepare a summary of any Biosafety issues to email to the IBC. Otherwise, the IBC meetings will remain the same for now.

OLD BUSINESS:

None

NEW BUSINESS:

1. 05-022 principal Investigator; [REDACTED] Project Title; [REDACTED]
[REDACTED] Approved by Chair 3/30/05.

Previously reviewed and approved by the Chair, the PI will be using human cell lines, chick embryos and generating non replicating virus,. Everything treated is biowaste, bleached before disposal. If anyone has any concerns please let [REDACTED] know. Otherwise it is approved.

2. 05-006 principal Investigator; [REDACTED] Project Title; [REDACTED]

Approval with the BIACUC is on file in the BIACUC office. Some concerns regarding the requirements for an animal BSL2 facility. [REDACTED] questioned the two lines of study, what if the cell culture fails? (Questions were submitted to the PI, replied, sent to IBC members for review, and approved and signed by the Chair). See file for details.

There followed a discussion of the Biosafety forms, adding a bullet for yes or no responses, making it a pdf file that can be saved and secured with [REDACTED] and [REDACTED] said that electronic files can be made secure with the adobe pdf file. Web based program for online submission would be nice, but involved.

Meeting adjourned.

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

DECEMBER 15, 2004

Present:

[REDACTED]
[REDACTED] Beth Reeves, [REDACTED]

Absent:

CONSIDERATION OF THE MAY 5TH, 2004 MINUTES:

The minutes for the May 5, 2004 meeting were approved.

ANNOUNCEMENTS:

1. Appointment of [REDACTED] to the IBC.
2. Letter from the NIH regarding rDNA registration and IBC's.
3. [REDACTED] department; tiger remains.
4. Exposure incident in Medical Microbiology.
5. Progress report on renovations to [REDACTED] and [REDACTED]
6. Review drafts of annual project renewal form and revised biosafety form.
7. Discussion of USDA inspection December 17th at 1:00 pm with [REDACTED]
[REDACTED]
8. Discussion of LSCC brochures for new faculty and a website.
9. Biosafety presentation by Beth Reeves at the Research Symposium December 8, 2004.

OLD BUSINESS:

1. Discussion of annual project renewal form.

It was suggested that multiple lines be added under Project Titles.

NEW BUSINESS:

1. Discussion of minutes sent to Sunshine Project,

It was requested that copies of the didacted minutes be sent to the IBC members

as well as [REDACTED] Approved.

2. [REDACTED] officially appointed as a member of the IBC.

3. Discussion of tiger remains from [REDACTED]

Orange biohazard bags containing the remains of a tiger from the department of [REDACTED] were left curb side by graduate students. IUPD Officers were notified, they contacted EH&S, and remains were transferred to the walk in freezer at [REDACTED] for disposal in accordance with OSHA regulations.

[REDACTED] inspected the freezer in [REDACTED] and reported that the animals are deceased when received, and are obtained from various sources.

It was suggested by [REDACTED] that Standard Operating Procedures be reviewed with LAR concerning the disposal of animal tissues/bones from [REDACTED] and that a policy be developed to deal with the use of dead animals and biosafety issues that might occur in other departments.

4. Discussion of Medical Microbiology incident exposure

A student in the Medical Microbiology laboratory accidentally splashed an "unknown" bacterial culture into their eyes, was directed to rinse immediately for 15-20 minutes and then strongly advised to report to the Student Health Center for evaluation and possible treatment but initially refused to go. Student eventually went to the Student Health Center, was evaluated and released.

The "unknown" culture was determined to contain *Pleisiomonas* species that has been known to cause eye infections. Initial medical evaluation and follow-up visit showed no signs of infection.

Student strongly cautioned to wear protective eyewear when entering the Medical Microbiology laboratory from now on.

5. [REDACTED] raised the question of liability forms for students.

[REDACTED] to talk with Larry Stevens about a form to cover students involved in an incident exposure/accident.

It was reiterated by the IBC that students are to be required to wear safety glasses even if the work they are doing does not require the use of a Biosafety Cabinet.

6. [REDACTED] discussed the renovation and use of [REDACTED] and [REDACTED]

[REDACTED] is considered to be under the umbrella of the Indiana Molecular Biology Institute (IMBI), and [REDACTED] is under the umbrella of the Biology department. It is anticipated that [REDACTED] will be ready by Spring of 2005 for new equipment.

[REDACTED] suggested centralizing the materials needed for both rooms.

7. USDA inspection

[REDACTED] to be inspected by USDA inspectors for possible use by [REDACTED]

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

MAY 5TH, 2004

Present:

[REDACTED]
Beth Reeves, [REDACTED]

Absent: [REDACTED]

CONSIDERATION OF THE CONSIDERATION OF THE DECEMBER 17TH MINUTES:

The minutes for the December 17th meeting were approved.

ANNOUNCEMENTS:

1. Sunshine Project discussion, led by [REDACTED]

Discussion followed of the Sunshine Project, how they were unhappy with the lack of cooperation by the IBC's nationwide, not just ours. 45% of those requested sent dictated minutes. Members to be sent copies of the dictated minutes for review. IBC decided at this time to continue keeping detailed minutes.

2. Analysis of fossilized human remains for DNA from formerly infectious agents.

Discussion followed of the use of very short fragmented nonfunctional DNA with a very low risk of viability. [REDACTED] will be conducting fingerprinting PCR assay studies eventually. [REDACTED] asked where would the samples be obtained from? Perma frost, contiguous eight? [REDACTED] commented that [REDACTED] has been doing TB fingerprinting, and there are publications indicating that no viable organisms are retrieved from samples.

Conclusion; as a committee, the IBC should develop guidelines for what research would fall in this category; ask [REDACTED] to provide literature on viability studies; check with the NIH guidelines; diagnostic specimens vs. infectious specimens.

3. Presentation of draft of the Biosafety annual report form.

Discussion followed concerning including the protocol number on grant submissions and developing a biosafety packet to distribute to new faculty before they arrive on campus. All research involving biological materials needs to be registered with the biosafety office even if the work is considered exempt.

4. Will suggest that the SRS modify the route sheet to include the protocol #.
Steve Martin agreed that this needed to be done.

OLD BUSINESS: See announcements.

NEW BUSINESS:

1. 04-003 Principle Investigator; [REDACTED] Project title [REDACTED]
[REDACTED] Approved.
2. 04-005 Principle Investigator; [REDACTED] Project Title; [REDACTED]
[REDACTED] Approved.
3. 04-004 Principle Investigator [REDACTED] Project title; [REDACTED]
[REDACTED] Approved.

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

DECEMBER 17, 2003

Present:

[REDACTED] Beth Reeves, [REDACTED]

Absent:

CONSIDERATION OF THE SEPTEMBER 10, 2003 MINUTES:

The minutes for the September 10, 2003 meeting were approved.

ANNOUNCEMENTS:

1. [REDACTED] appointment of [REDACTED] as community member replacing [REDACTED]
2. Administrative restructuring, creation of Laboratory Safety Committee
3. Radiation Safety under RUGs, Biosafety under EHS
4. Introduction of [REDACTED] to IBC
5. Approval of September 10th 2003 minutes
6. Question raised by [REDACTED] concerning Security issues addressed in security plan required for [REDACTED] and privacy issue being adequately addressed

OLD BUSINESS:

1. Discussion of [REDACTED] Medical Microbiology, course almost completed, went well.
2. Discussion of minutes being detailed, and availability to public if requested. [REDACTED] raised issue of animal use. Broadbrush set of minutes and set of [REDACTED] detailed minutes for IBC. Will consult University Counsel. Sensitivity to locations and biological agents also considered.
3. [REDACTED] now completely catalogued stored and secured, checked out by appropriate authorities. Acquisition of stock cultures development of [REDACTED] request form by [REDACTED]
4. Will post description of culture collection, who is responsible for it, mechanism for requesting a strain on web site. [REDACTED] has agreed to act as curator.

5. Only [REDACTED] Beth Reeves, and a couple of other faculty members will have access to the collection. Also post strain request form on website.
6. Question for the committee, should this be posted on the IBC website or is it an internal biology issue.
7. [REDACTED] proposes leaving it as a biology specific set of pages and administration. Beth Reeves would receive copies, off campus or on campus. [REDACTED] raises issue of transportation according to IATA regs. Most of the requests come from in Biology, very small number off campus.
8. Suggestion made that biosafety level be requested on the strain request form.
9. Curator will keep track of how many vials are used, remain, etc. [REDACTED] will modify database.
10. Protocol for destruction of BSL2 organisms, same as for use in any lab, so that the biosafety officer knows when organism is disposed of. If the FBI came over and looked at the list of those strains requested, would the documentation be enough? Every lab that requests a BSL2 organism would be responsible for documenting the use and or destruction of the organisms.
11. Only Research Scientists or students under their guidance would have access. Any requests for off campus distribution would have to be reviewed by Curator and possibly the microbiology oversight committee.

Distinguish between BSL1 and BSL2 organisms requests. Committee wouldn't have to comment on exempt or BSL1 requests, but all BSL2 or above to be distributed off campus must be reviewed by the oversight committee.

12. Discussion of Guidelines for shipping and receiving of microorganisms document; list of organisms that fall under the guidelines, post on website. All BSL2 or higher organisms must be received or shipped out via the biosafety office. If any unexpected BSL2 organisms are received, immediately report to Biosafety Officer. No BSL3 pathogens at this time, no select agents on Bloomington campus at this time, delivery of any of those organisms at this time is a federal offense. Anticipated timeline for CDC site registration [REDACTED]
13. [REDACTED] mentioned we need a particular select agent to develop a specific protocol, security issues, etc., specific for a "select agent".
14. Facilities in [REDACTED] and [REDACTED] in [REDACTED] mentioned in minutes last time, responsibilities ambiguous, now there is an oversight committee chaired by [REDACTED] in charge of these two rooms. Waiting for work order to put in an operation foot

pedal for the sink in [REDACTED] and an eyewash. Air handling dependent on when foot pedal is finished. [REDACTED] system for inner door in [REDACTED] Discussion followed on how to insure packages are accounted for in the [REDACTED]

15. Discussion of personnel standards and background checks, [REDACTED] requests copy of regs be sent to him. Beth Reeves agreed to send them.
16. Eventually there will be two separate [REDACTED] buildings. One could be for [REDACTED] one for non [REDACTED]
17. Document that requestor of a BSL2 organisms from IU, has approval from that institution to receive that organism. Contact Biosafety officer of the receiving institution before shipment of any BSL2 organisms.
18. Inclusion of toxins on guidelines for shipping receiving microorganisms, a separate set of guidelines for toxins.
19. Discussion of annual update biosafety form, template from Iowa State, Beth Reeves will prepare a template for consideration at next meeting.

NEW BUSINESS:

1. Protocol # 03-005 Amendment to [REDACTED] Principle Investigator; [REDACTED] Approved.

[REDACTED] will be requesting an exempt organism from a researcher in Germany. No known limit on the amount of toxin kept in each lab.

2. Protocol #03-033 Principle Investigator; [REDACTED] Approved. Comments on how well done protocol is, may use it as a template for others to follow.

All those working with the virulent pneumococcal strain will be required to receive the pneumococcal vaccine, but not the Hepatitis B vaccine. It will be made available, but not required.

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

SEPTEMBER 10, 2003

Present: [REDACTED] Beth Reeves [REDACTED]
[REDACTED]

Absent: [REDACTED]

CONSIDERATION OF THE JUNE 11, 2003 MINUTES:

The minutes for the June 11, 2003 meeting were approved.

ANNOUNCEMENTS:

1. [REDACTED] should be completed by the end of next month at which time all work done in [REDACTED] will be temporarily transferred to [REDACTED]. [REDACTED] is roughly divided into two sections, one virology and one bacteriology. Anticipated completion of the renovations to [REDACTED] up to [REDACTED] standards, hopefully by the end of the semester.
2. Under the IMBI umbrella, but oversight is provided by the IBC and [REDACTED]
3. Only those approved by the IBC will be granted access to [REDACTED] and [REDACTED]. Sign in sheets will be required in [REDACTED] and [REDACTED].
4. [REDACTED] asked about the possibility of animal facilities in the [REDACTED] laboratory. Animals in [REDACTED] may be designated as such once the [REDACTED] is built. In the event that a newly recruited faculty member needs [REDACTED] animal facilities, the [REDACTED] lab can be temporarily retrofitted to accommodate this need. In the longer term, the [REDACTED] lab may be solely for [REDACTED] animal use, and the new [REDACTED] lab will be for all [REDACTED] activities not involving animals.
5. Discussion for development of an annual review form. [REDACTED] pointed out that this would actually reduce the paper work for those investigators completing a new biosafety form for each, yearly non-competitive NIH renewal. [REDACTED] suggested submitting a biosafety form with an umbrella title, and listing which grant titles are covered by that project. [REDACTED] will send [REDACTED] a copy of what he submits to NIH. [REDACTED] suggested that regulations are going that way, to require a yearly review. That is currently the way it is done with human subjects and the IACUC.
6. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
7. Security issues in [REDACTED] and [REDACTED] discussed. [REDACTED]

[REDACTED]

OLD BUSINESS:

None

NEW BUSINESS:

1. Protocol # [REDACTED]
Approved.

[REDACTED]

[REDACTED] suggests a section added to the biosafety form which addresses what type of waste is generated. He will compose the material and email it to the members for review.

2. Protocol # [REDACTED]
 - a. Offering of 2002 class cancelled by biology department last year.
 - b. This course had to be offered to meet students requirements to graduate.
 - c. [REDACTED] only accessible [REDACTED] and his AI's. Lab access restricted to those taking the course and supervised times to work in the lab. [REDACTED] states that there is a functional eyewash in the lab. [REDACTED] volunteered to look at it after the meeting, and found that it is functional.
 - d. Review of [REDACTED] lab manual by the Microbiology Curriculum Committee and suggestions summarized in letter attached to Biosafety form.
 - e. Students are not to work with [REDACTED] They are to be demo's only prepared by [REDACTED] and or the AI's [REDACTED]
 - f. Replace all pathogens with nonpathogenic strains if at all possible and document. It is suggested that for next year, where possible, replace all pathogens with ATCC attenuated strains.
 - g. Opportunistic pathogens BL2 and lower may be handled by the students in a BSL2 hood.
 - h. Human samples- discussion of mock samples, use of animal samples. No use of human samples other than self sampling as outlined in the biosafety form.
 - i. [REDACTED]
 - j. Limiting [REDACTED] to Microbiology students that it is truly beneficial to, a more

- specialized group. 211 and 200 should be requirements.
- k. [REDACTED] suggested case studies be implemented next year.
 - l. Self sampling may be done, but no sampling of anyone else. All cultures will be inspected by [REDACTED] and or the AI's, any potential pathogens will not be worked with by the students.
 - m. Access limited by [REDACTED] and [REDACTED]
 - n. Immunocompromised or at risk individuals advised not to take the course and other alternatives should be made available.
 - o. [REDACTED] demo only.
 - p. After each organism list which lab it is used in and, in general, what manipulations are performed with it (eg. streaking on media, gram stain, etc.)
 - q. Source of organism ([REDACTED] will help [REDACTED] obtain ATCC strains for next year)
 - r. Autoclave available in the room for biohazardous waste.
 - s. Swabs must be disposed of in biohazard bags and final processing through EHS.

[REDACTED] may continue teaching the course this year as is with the following changes;

- [REDACTED] demo only.
- Use [REDACTED] for demonstrating streaking of plates rather than [REDACTED]

Record any use of [REDACTED] from [REDACTED] in [REDACTED]

3. Guidelines for shipping and receiving – draft review

- a. Discussion of the guidelines.
- b. All BSL-1 transfers recorded.
- c. BSL-2 and above must be routed through Biosafety Office either sent from or received by IU scientists.
- d. [REDACTED] pointed out that APHIS requirements are more stringent in some areas for transfer for certain plant pathogens crossing state lines. He will obtain information on these restrictions
- d. Discussion of drafting guidelines for on campus, in and between building transfers.
- e. Discussion of implementation of an expanded Biosafety website with information on CDC/APHIS categories for pathogens.

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

JUNE 11, 2003

Present:

[REDACTED] Beth Reeves, [REDACTED]

Absent:

CONSIDERATION OF THE MARCH 5, 2003 MINUTES:

The minutes for the March 5, 2003 meeting were approved.

ANNOUNCEMENTS:

1. Committee membership changes
 - a. [REDACTED] step off
 - b. New IBC committee members – [REDACTED]
2. Discussion led by [REDACTED] concerning the renovation of [REDACTED] and [REDACTED] and coordinating the timing so that no work in [REDACTED] would be interrupted.
3. A question was raised concerning where the funds were coming from for the renovation and [REDACTED] stated that there were funds for this purpose obtained through RUGS competition by the Indiana Molecular Biology Institute.
4. Discussion of the new [REDACTED] structure, with reference to the architects contracted to build the [REDACTED] facility are the same as those which built the facilities at IUPUI.
5. [REDACTED] suggested considerations be made when designing the hard ducting to allow for future growth/changes in [REDACTED]
6. Tentative future meetings for the IBC; end of December, beginning of May, beginning September.

OLD BUSINESS:

None

NEW BUSINESS:

1. Protocol # 03-006

Approved.