



UNIVERSITY
OF
LOUISIANA
L a f a y e t t e

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April 25, 2006

The Sunshine Project
Attn: Edward Hammond, Director
P.O. Box 41987
Austin, TX 78704

Mr. Hammond:

Please find enclosed minutes of the Institutional Biosafety Committee at the University of Louisiana at Lafayette in response to your request of March 15, 2006. Minutes of all official IBC meetings that occurred between May 1, 2003 and the date of your request are included.

We are happy to comply with NIH guidelines that require IBC minutes be made available to the public upon request. Please be aware that charges to cover institutional costs may apply to future requests depending on the number of pages that comprise the request.

Sincerely,

Carl D. Frantz, Director
Office of Research and Sponsored Programs

Minutes
Institutional Biosafety Committee Meeting

March 29, 2004, 10:00 am

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Members present: Dr. Walter Comeaux, Dr. Tom Pesacreta, Dr. Don Ennis, Dr. John Dankert, Heather Gonsoulin, Joey Pons, Dr. Paul Klerks. Also present: Dr. Carl Frantz (ORSP / university liaison).

Excused: Dr. Gus Gallo, Dr. Timothy Croughan

1. IBC Chair called the meeting to order. All attending members were introduced and the Director of Research and Sponsored Programs affirmed the University's position to support decisions made by the IBC.
2. The IBC Chair introduced the committee to federal regulations and documents available to assist the IBC in making decisions (NIH, BMBL, CDC, and OBA). Members are asked to subscribe to the OBA listserv and are required to view the training slide presentation on the OBA web site (http://www4.od.nih.gov/oba/IBC/IBC_conf_links.htm). Members were provided hardcopies of the NIH guidelines for recombinant DNA research and BMBL books will be distributed to the IBC once they are received.
3. The IBC Chair and the Director of Research and Sponsored Programs will schedule an outside reviewer to visit with the IBC for the Fall 2004 semester. In the meantime, the IBC shall determine if the scope of that visit shall include training.
4. The confidentiality agreement between IBC and the University was presented and discussed. Specifically, NIRC researchers are asked to exclude from their IBC applications confidential information that is not directly related to the IBC review. IBC members are required to sign the confidentiality agreement and submit this document to the ORSP office. The Director of Research and Sponsored Programs will send the confidentiality agreement to the IBC members not in attendance and will distribute a duplicate copy to each member.
5. The Director of Research and Sponsored Programs will handle registering the IBC with NIH as soon as possible.
6. The protocol for reviewing proposals was discussed among the IBC. The Biosafety Officer moved to allow the chair the authority to decide if an application should undergo an expedited review or a full review. An IBC member seconded the motion. The committee voted unanimous in favor of this motion. Thus, the IBC Chair will make the initial decision. Generally, recombinant DNA proposals not exempt from NIH, any proposal involving a

Select Agent, and any proposal involving BSL-3 research shall have a full review.

7. The UL Lafayette IBC Policies and Procedures document was reviewed at length. The University Safety Officer and the IBC Chair noted modifications decided by the committee for inclusion in the first official edition of this document. The University Safety Officer shall incorporate these modifications and submit to The IBC Chair for approval. An IBC member moved to adopt the document as written (with modifications). The Biosafety Officer seconded the motion and the committee voted unanimously in favor. The adopted document shall be distributed to all committee members in the near future.
8. The application forms were presented to the committee. An IBC member moved to adopt the application forms. An IBC member seconded the motion and the committee voted unanimously to adopt these forms.
9. The committee decided that University research already approved and scheduled for completion before October 1, 2004 will not be reviewed by the IBC. University research already approved and scheduled to continue beyond October 1, 2004 will be reviewed by the IBC. As of April 15, 2004, all new research using biological agents will have to undergo IBC review.
10. IBC meetings shall be scheduled on the last Monday of every month at 10:00 am at a location to be determined. The committee shall meet next month (April 26, 2004, again at the UL Foundation conference room) to ensure that everyone is comfortable with the policies and procedures adopted during the first meeting. In the future, the monthly meeting will generally be canceled if there are no applications pending for a full committee review.
11. The IBC meeting was adjourned at 12:30 pm.

Minutes
Institutional Biosafety Committee Meeting
April 26, 2004, 10:00am

Members present: Dr. Walter Comeaux, Dr. Don Ennis, Dr. John Dankert, Heather Gonsoulin, Dr. Paul Klerks, Dr. Timothy Croughan. Also present: Dr. Carl Frantz (ORSP/University liason).

Excused: Dr. Gus Gallo, Dr. Tom Pesacreta.

- a) The IBC Chair called the meeting to order.
- b) The IBC Chair introduced the first order of business as the review and approval of the minutes from the previous meeting, March 29th. There were no corrections. An IBC member moved to accept the minutes. The Biosafety Officer seconded the motion. The committee voted unanimous in favor of this motion.
- c) The IBC Chair introduced the next order of business as the review of the IBC application NIRC04-03. The PI for the application was asked to attend the meeting to present her application and answer questions regarding the application. An IBC member requested the IBC approval certification from the sponsor company be included for this application and all others that are done through NIRC. The PI agreed to this revision. Also discussed was the term "blanket approval". Two IBC members expressed concern over an approval being used to cover all vaccine work at NIRC. The PI explained that by "blanket approval" it was meant for the vector systems specifically addressed in the application NIRC04-03. The term was to cover multiple vectors in one application instead of a single vector per application. The PI was thanked for her explanation and allowed to leave the meeting. The Biosafety Officer moved to approve the application pending documentation of IBC approval from the sponsor. An IBC member seconded the motion. All committee members unanimously voted in favor of the motion.
- d) The next item discussed was the need to review studies for which the active study phase is over, but the study organisms remain under observation. An IBC member explained the situation that occurs at NIRC where animals are kept beyond the study period for months or even years and their health status is monitored but no active experimentation is being conducted. The committee discussed including in the policy and procedure document, wording that would exclude the situation where the study organisms are only being monitored or maintained, from the annual renewal requirement. An IBC member moved to include the exclusion for monitoring and maintenance of study organisms in the policy and procedure document. The Biosafety Officer seconded the motion. All committee members voted unanimously in favor of the motion.

- e) The issue of “blanket approval” was discussed further and the committee decided that it would be handled on a case by case basis whether an approval would be given for single or multiple experiments.
- f) The IBC policy and procedure document was revisited to ensure that the changes that were made at the previous meeting were indeed what was intended. An IBC member moved to adopt the IBC Policy and Procedures document. An IBC member seconded the motion. All committee members voted unanimously in favor of the motion.
- g) New business:
 - a. An IBC member asked the committee how it would like to handle monoclonal antibody use. The committee discussed the definition of biological agent as defined in the policy and procedure document and decided that monoclonal (or polyclonal) antibody was not intended to be included in the definition. Therefore the use of antibodies would not be required to be submitted as an application to the IBC.
 - b. An IBC member questioned the Committee about liability in regards to approving a study and then being sued (the University or the individual sponsor) for someone being injured or infected. The Director of Research and Sponsored Programs stated that he would look into this issue and report back to the Committee.
- h) The subject of review of the IBC Policy and Procedure document and training for IBC members was revisited. The Biosafety Officer stated that he would ask a colleague at Arizona State if he could review the IBC documents. An IBC member stated she would look into training classes available for IBC members.
- i) The Committee will tentatively schedule the next meeting May 31st at 10:00am at a location to be determined. The meeting will be cancelled if there are no applications pending for full review by the Committee.
- j) The IBC meeting was adjourned at 11:30am.

Minutes
Institutional Biosafety Committee Meeting
June 28, 2004, 10:00 am

Members present: Dr. Walter Comeaux, Dr. Tom Pesacreta, Dr. Timothy Croughan, Dr. Don Ennis, Dr. John Dankert, Heather Gonsoulin, Joey Pons, Dr. Paul Klerks, and Dr. Gus Gallo. Also present: Ruth Landry (ORSP).

Excused: none

1. The IBC Chair called the meeting to order. All attending members were introduced to the representative from the Research Office, who described her role with the University Office of Research and Sponsored Programs and how that role affects the IBC.
2. The IBC Chair presented the minutes from the April 2004 meeting and asked for any comments or suggestions. An IBC member expressed a concern for IBC exposure to liability. The University Safety Officer will look into this matter and address the issue at the next IBC meeting. The minutes of the April 2004 IBC meeting were approved.
3. Proposal NIRC04-04 was presented to the committee for comments and questions. The PI was unable to attend – An IBC member addressed questions to the IBC on her behalf. The Biosafety Officer asked for a clarification of questions 8 and 22 and was provided an explanation by an IBC member. An IBC member inquired about the shipping of biological materials and was provided an answer from an IBC member in this regard. The Biosafety Officer noted that, in the future, the PI should provide clear background information that is relevant to the proposal description. The IBC Chair shall request this clarification from the PI in writing. The Biosafety Officer moved to approve this proposal pending a clarification of questions 8, 13, and 22. An IBC member seconded the motion. The IBC voted unanimously in favor.
4. Proposal NIRC04-05 was presented to the committee for comments and questions. The PI was unable to attend the meeting and questions were addressed by an IBC member on her behalf. The IBC Chair asked about sample/material disposal (“currently incinerated on site but alternatives are being evaluated”). An IBC member asked about accessing the blood samples. An IBC member answered each of these questions using the proposal documentation and methodology, and general NIRC policies and procedures. The Biosafety Officer asked about the infectiousness of the biological material described in question 8. An IBC member replied that some statements in question 8 were not completely applicable and supported this with the answers to questions 13 and 22. The Biosafety Officer requested a clarification of

question 17 to which the IBC member speaking for the PI could not reply. The University Safety Officer inquired about question 27 – facility inspections. The BSO has inspected the facilities at NIRC and another site inspection will be scheduled for some time in August. An IBC member moved for approval of the proposal pending a clarification to question 17. An IBC member seconded the motion and the IBC voted unanimously in favor.

5. Proposal NIRC04-06 was presented to the committee for comments and questions. The PI was unable to attend the meeting and questions were addressed by an IBC member on her behalf. The Biosafety Officer moved to approve the proposal without any clarifications. An IBC member seconded the motion and the IBC voted unanimously in favor.
6. The IBC Chair announced that one expedited proposal was approved since the previous meeting; further information on the proposal was included in a footnote to the minutes.
7. A discussion ensued regarding public access to IBC meeting minutes. An IBC member offered some background information on this subject. A decision was made to make minutes available to the public upon request, but not automatically posted on a webpage. Any redaction of minutes will be handled on a case-by-case basis.
8. The committee discussed IBC training. The IBC Chair suggested that the committee view a webcast on BSL-3 safety available through the CDC website (URL listed in minutes). The committee is also looking into the idea of bringing in someone from the outside to conduct a site-specific training session.
9. An IBC member indicated that he will be leaving the IBC effective with the beginning of the UL Lafayette Fall semester. An IBC member from NIRC will be joining the IBC effective August 18.
10. An IBC member asked the committee if it would be a good idea to require a PI to attend the IBC meeting that reviews his/her proposal. The consensus was that it would benefit the PI to attend (would speed up an IBC decision), but that it may be impossible at times for a PI to attend. No motion was offered; IBC members generally felt it best to maintain the current protocol (in which a PI is invited to attend, but attendance not being a requirement for proposal review) for the time being and revisit this issue after further experience with it.
11. The next IBC meeting will be July 26, 2004, 10:00 am at Parker Hall unless there are no proposals to review.
12. The meeting adjourned at approximately 11:30 AM.

Minutes
Institutional Biosafety Committee Meeting
July 26, 2004, 10:00 am

Members present: Dr. Walter Comeaux, Dr. Tom Pesacreta, Dr. Timothy Croughan, Dr. Don Ennis, Heather Gonsoulin, Joey Pons, and Dr. Paul Klerks (Chair). Also present: Ruth Landry (ORSP).

Excused: Dr. August Gallo, Dr. John Dankert

1. The IBC Chair called the meeting to order. Prior to the meeting, the IBC Chair had distributed copies of the minutes from the June 2004 meeting and asked for comments or corrections. No corrections were proposed and the minutes of the April 2004 IBC meeting were approved as distributed.
2. Proposal BIOL04-01 was presented to the committee for comments and questions. The PI briefly discussed the scope of the proposal with the committee. An IBC member inquired about the safety of a sudden release of an agent. The PI replied by citing standard BMBL procedures to be used in this proposal. The IBC Chair inquired about growing new bacteria for this proposal. The PI will use existing libraries of bacteria for this experiment. The issue was also brought up that while this research uses genes from a select agent, this research does not fall in the select agent category as the genes used do not code for toxins. The committee decided to vote on all three proposals by this PI after their subsequent discussion (see #3, 4, and 5).
3. Proposal BIOL04-02 was presented to the committee for comments and questions. The PI indicated that bacteria used for this experiment is infectious and therefore warrants BSL-2 protocols. An IBC member inquired about cleaning procedures for this experiment to which the PI responded that everything will be autoclaved. An IBC member inquired about injecting any material directly into fish – the PI stated that this would not happen. An IBC member asked about any health risk associated with the green florescent protein (GFP) – the PI responded that none are known. Moreover, there is little chance of the GFP gene spreading, as expression of the gene is an energy drain for the bacteria.
4. Proposal BIOL04-31 was presented to the committee for comments and questions. The PI provided a short overview of the research. BSL-3 protocols apply for this proposal because of the Select Agent involved. The University Safety Officer added more information about this proposal from a regulatory standpoint. CDC approval is pending (“30-day requirement”), and security clearance for PI, RO and students has been completed. The primary route of exposure was indicated to be via inhalation. The PI and RO explained the presence of alarms and back-ups in case of failure of an air-handler. The issue

of follow-up following a medical examination of one of the researchers (after a possible accident) was addressed (“will be done by an infectious disease specialist”).

5. The Biosafety Officer excused himself from the vote (conflict of interest). An IBC member moved to accept application BIOL04-01 as submitted and another IBC member seconded the motion. This application was approved unanimously (6-0). An IBC member moved to accept application BIOL04-02 and another IBC member seconded the motion. This application was approved unanimously (6-0). The University Safety Officer moved to accept application BIOL04-03 pending the CDC approval (with documentation to the IBC) and another IBC member seconded the motion. This application was also approved unanimously (6-0).
6. There were no expedited applications processed since the previous meeting.
7. The committee re-visited the issue of making the minutes of the IBC meetings available to the public. An IBC member moved to make the committee minutes (redacted, where necessary) available to the public upon request, but not to post these on any University web page. An IBC member seconded the motion. The committee voted unanimously in favor of this motion. This decision will be reflected in the next revision of the IBC Policies and Procedures document.
8. The University Safety Officer presented a letter from the Louisiana Office of Risk Management ensuring the IBC that ORM will provide liability coverage on behalf of all the committee members (including non-state employees while they are performing duties as part of the committee). ORM will also provide defense for the committee if a lawsuit claiming disclosure of private information was alleged. A copy of the memo from ORM was distributed to all members.
9. Concerning any new IBC business: The Biosafety Officer and The IBC Chair are in the process of designing a universal IBC inspection document to be used by the BSO when inspecting facilities used in IBC-covered research.
10. Concerning any old IBC business: The Biosafety Officer and The representative from the Research Office are working together to identify a consultant to review the IBC procedures and provide training.
11. The next IBC meeting will be August 30, 2004, 10:30 am in the UL Foundation building unless there are no proposals to review.
12. The meeting adjourned at approximately 11:30 AM (motion by an IBC member, seconded by the Biosafety Officer, approved unanimously).

Minutes
Institutional Biosafety Committee Meeting
September 27, 2004, 10:30am

Members present: Dr. Walter Comeaux, Dr. Don Ennis, Heather Gonsoulin, Dr. Paul Klerks, Dr. Timothy Croughan, Dr. Patrice Frost, Joey Pons. Also present: Ruth Landry

Excused: Dr. Tom Pesacreta, Dr. August Gallo

1. The IBC Chair called the meeting to order, at 10:35.
2. The IBC Chair introduced the first order of business. The new and exiting members were announced. Terms expired for two IBC members and the University Safety Officer. An IBC member and the University Safety Officer have been appointed to a new 3-year term. An IBC member was introduced as the new member.
3. The IBC Chair then introduced the minutes from the previous meeting of 7/26/04 for review and approval. Copies of the minutes had been distributed prior to the meeting. There were no corrections to the minutes. The minutes were approved as distributed.
4. The IBC Chair introduced the next order of business as the review of the IBC application NIRC04-07. The PI for the application was asked to attend the meeting to present her application and answer questions regarding the application. The Biosafety Officer suggested modifying item #8 to include type of insert in description of research. He also requested a more precise number be given for item #18. The IBC Chair requested more information on the strain of VEE that is used in the study. The PI agreed to provide the information to the committee.
5. Also discussed while the PI was in the room was the change request for application NIRC04-03. The committee requested the following information regarding the change. What is meant by "aerosols may not be generated in the open" in the letter from the sponsor, is it in the lab or in the animal room? What is the liability to the University if the level is decreased? How do other IBCs that the sponsor deals with decide to comply with this request to decrease the Biosafety Level? The PI agreed to attempt to obtain the information requested. She was then allowed to leave the meeting.
6. The Biosafety Officer moved to approve application NIRC04-07 pending documentation of the information requested. An IBC member seconded the motion. The University Safety Officer abstained from voting, while all other committee members voted in favor of the motion.

7. The committee decided to not proceed on the change request for application NIRC04-03 until further information could be obtained from The PI. The committee will table the change request until the next meeting.
8. There were no expedited applications processed since the last IBC meeting.
9. The representative from the Research Office presented a summary of IBC reviews in the past year. She will continue to maintain these statistics. The representative from the Research Office is also responsible for notifying University Principal Investigators of renewal times for IBC continued approval and/or review.
10. The IBC Chair discussed the CDC/NIH web-cast and several committee members commented on the PowerPoint presentations.
11. The representative from the Research Office presented names from 3 potential consultants (along with Curriculum Vitae from 2 of them) that the University could hire to perform IBC training and in-service. The IBC would be able to provide suggestions and guidance to the successful consultant in order to cater the training to its needs. Possible dates for this training would be in late January 2005 or early February 2005. University principal investigators and researchers would be invited to at least a portion of this training. The IBC will further review these consultants and continue this discussion at the next meeting.
12. The next IBC meeting will be October 25, 2004, 1:00 pm in the UL Foundation building unless there are no proposals to review.
13. The meeting adjourned at approximately 11:30 AM (motion by an IBC member, seconded by the Biosafety Officer, approved unanimously).

Minutes
Institutional Biosafety Committee Meeting
October 25, 2004, 1:00 pm

Members present: Dr. Walter Comeaux, Dr. Don Ennis, Heather Gonsoulin, Dr. Paul Klerks, Dr. Timothy Croughan, Dr. Patrice Frost, Dr. Tom Pesacreta, Joey Pons. Also present: Ruth Landry

Excused: Dr. August Gallo

1. The IBC Chair called the meeting to order, at 1:05 pm. Minutes of the September 27, 2004 meeting were accepted as written and distributed prior to the meeting.
2. The IBC Chair introduced the first order of business, to review the request to change the risk assessment of the previously approved NIRC04-03 application. An IBC member was informed of the previous discussion held in September in his absence.
3. An IBC member indicated if the IBC were to allow the risk assessment to be downgraded to ABSL-1, NIRC SOPs for this type of work allow for a greater level of protection than BMBL ABSL-1 protocols, but do not follow all types of BMBL ABSL-2 protocols. Examples of that include restricted access already in place (ABSL-2), but Tyvek ® suits and respirators are not worn.
4. Documents from the Sponsor were discussed in relation to this issue. The University Safety Officer indicated that from a risk management standpoint, it would be prudent for the IBC to weight its decision on these matters using accepted federal standards (i.e. NIH, CDC, BMBL, etc.) as opposed to using the opinion of a Sponsor or a vendor (i.e. someone who has the potential to profit from the IBC decision).
5. An IBC member indicated that the Sponsor's BSL-2 protocols are above and beyond BMBL standard BSL-2 practices. An IBC member also indicated that BMBL practices for ABSL-2 work do not require the use of a respirator unless there is a danger of aerosol production. Further discussion clarified that the actual procedural changes that the PI envisioned for the Change Request on NIRC04-03 are accommodated within the BMBL regulations for BSL-2 work (and thus do not require a downgrade of the containment from BSL-2 to BSL-1).
6. The Biosafety Officer made a motion to deny the request to change the proposal from ABSL-2 to ABSL-1, and to require NIRC researchers to adhere to NIH and BMBL standards for ABSL-2 work for this proposal. This motion passed with a vote of 7-1. An IBC member voted against the motion on the grounds that it appeared to weaken the containment requirements (from the NIRC and the Sponsor ABSL-2 practices to the weaker NIH/BMBL ABSL-2 ones).

7. There were no expedited applications processed since the last IBC meeting.
8. The representative from the Research Office presented a resumé for a potential consultant that the University could hire to perform IBC training and in-service. After reviewing all of the applicants, the committee decided to rank them in preference for the IBC training. The representative from the Research Office will attempt to schedule this training for some time in February.
9. The next IBC meeting will be November 29, 2004, 11:00 am in the UL Foundation building unless there are no proposals to review.
10. The meeting adjourned at approximately 2:09 pm.

Minutes
Institutional Biosafety Committee Meeting
February 11, 2005, 2:00 pm

Members present: Dr. Walter Comeaux, Dr. Don Ennis, Dr. Paul Klerks, Dr. Patrice Frost, Dr. Tom Pesacreta, Dr. Gus Gallo, Joey Pons. Also present: Ruth Landry

Excused: Dr. Timothy Croughan, Heather Gonsoulin

1. The IBC Chair called the meeting to order at 2:12 pm. Minutes of the October 25, 2004 meeting were approved and accepted as written.
2. The IBC Chair introduced the first order of business, to review application NIRC05-01. The Biosafety Officer inquired about the definition of "SIV" and its applicability in either BSL2 or BSL3 facilities. The University Safety Manager further inquired about the discrepancy between questions 23 and 24, which address BSL3 practices in BSL2 facilities. An IBC member responded that within the current BMBL standards, language exist that specifically endorses utilizing BSL3 handling practices within BSL2 facilities for the applicable type of research. The BSO and chair read the applicable BMBL language and concurred with an IBC member. An IBC member further described some of the applicable handling practices such as: dosing SOPs, disinfection processes, PPE for workers, etc.
3. An IBC member inquired about any previous human exposures associated with this type of experimentation. An IBC member responded that the protocols to be used in the NIRC experiment take this risk into account.
4. An IBC member inquired about the experiment's relevance to lymph nodes. An IBC member responded that no needle biopsies will be performed in this experiment. An IBC member also mentioned to the committee that, in the future, applicants should answer question 18 in the form of a %.
5. The University Safety Officer moved that the IBC accept application NIRC05-01 provided questions 18, 24, and 28 are changed to reflect the issues previously mentioned in the meeting. The Biosafety Officer seconded the motion and the committee voted unanimously in favor.
6. Regarding expedited reviews, the IBC Chair mentioned one application currently under review that involves some BSL1 work to be performed by the PI (Biology). This application is undergoing expedited review.
7. The representative from the Research Office presented a tentative schedule of events and topics to be covered in the upcoming IBC training seminars. The committee commented on these and the representative from the Research Office

will implement these changes accordingly. The representative from the Research Office will email a final schedule of events to the committee. An IBC member suggested that some training for addressing chemical toxins and chemical protocols while performing experimentation at the University might be necessary. The committee will wait to see if these issues are addressed during the upcoming IBC training.

8. There was no new business to discuss with the committee. The next IBC meeting is scheduled for April, 4, 2005, 10:00 am, in the UL Foundation building unless there are no proposals to review.
9. The meeting adjourned at approximately 3:00 pm.

Minutes
Institutional Biosafety Committee Meeting
April 4, 2005, 10:00 am

Members present: Dr. Walter Comeaux, Dr. Don Ennis, Dr. Paul Klerks, Dr. Patrice Frost, Dr. Tom Pesacreta, Heather Gonsoulin, Joey Pons. Also present: Ruth Landry

Excused: Dr. Timothy Croughan, Dr. Gus Gallo

1. The IBC Chair called the meeting to order at 10:08 am. Minutes of the February 11, 2005 meeting (distributed prior to the meeting) were reviewed, one change was made (change in wording) and the minutes were approved as modified.
2. There was only one proposal for full review by the committee. The PI (who serves as the University Biosafety Officer) discussed his proposal (BIOL05-02) with committee members. An IBC member asked about dosing the animals and personnel precautions. The PI answered that there are SOPs to follow for this proposal including a sharps program and a PPE program.
3. An IBC member asked about questions 15 and 17 – wanted a further explanation of the vector systems. The PI answered these questions procedurally – there is no inherited risk associated with these questions.
4. An IBC member inquired about whether BSL-2 containment is sufficient to protect people against infection and long term carcinogenetic contamination. The PI answered this question by providing the BMBL and NIH Guideline reference that establishes his work as BSL-2 practices.
5. An IBC member asked about dose preparations and the logistics of getting these bacteria to the fish. The PI mentioned that bacteria are prepared in their BSL-2 facility. Bacteria are brought to the fish in a sealed container; the fish are anesthetized in one tank, transferred to another tank, injected with the bacteria, and then put into a holding tank for observation.
6. An IBC member asked about the need for a skin test for personnel working on this research. The PI stated that a test similar to the TB skin tests is not appropriate in this case. He will make sure personnel are aware of the risks associated with skin cuts and lesions. Further, the bacteria do not survive in temperatures of 37 degrees Celsius (human body temperature).
7. An IBC member indicated two (2) typographical errors on this proposal.
8. The University Safety Manager asked if the SOPs for this proposal parallel the SOPs currently in place for the Select Agent work being done; to which the PI answered “yes”. The IBC Chair indicated that inspection of the facility would

have to be done by someone other than the BSO (The Biosafety Officer).
[NOTE: INSPECTION OF THIS FACILITY WAS DONE BY THE IBC
CHAIR AND THE UNIVERSITY SAFETY OFFICER ON 4/4/05]

9. The committee excused The Biosafety Officer for a vote. An IBC member moved to accept the proposal; another IBC member seconded the motion. The committee voted unanimously (6-0) to accept the proposal. The Biosafety Officer was asked to return to the meeting.
10. The IBC Chair indicated that there was one expedited review and a renewal application. The expedited review had been approved. The renewal was approved by IBC Chair and BSO (since there were no deviations from the original application and no adverse effects during the project period).
11. The committee discussed the training visit by the consultant, and suggestions made for changes to the IBC Policies and Procedures document and application forms. The changes under a - c will be made to the main application form (IBC-APPL-1), while the changes under d - e will be made to the IBC policies and procedures document.
 - a. Question 18 – change to “If the vector is a virus other than a phage, what percentage of the viral genome is present?”
 - b. Question 20 – change to “Will transgenic animals be produced and/or used?”
 - c. An additional question for page 3 of the form – “Does this proposal require approval from the IACUC committee? (YES or NO) Also, “If yes, indicate the status of that approval or give the approval number.”
 - d. In several instances where the policies and procedures document refers to “research involving biological agents”, this will be changed to “research involving biological agents and/or recombinant DNA”.
 - e. In the glossary of terms section, in the section on Select Agents, the first part of the sentence “Depending on the agent, researchers must register with the either the CDC or USDA through” will be replaced by: “Researchers must register with the CDC through”

The IBC Chair will make these changes to the documents.

12. Also discussed was the issue of whether or not to make annual inspections of University facilities performing work with biological agents. The committee decided that researchers are expected to follow federal standards, which also govern conditions within a facility. For now, the committee will continue to implement its “periodically and as needed” policy.
13. There was no old business to discuss.

14. Regarding new business, the IBC Chair distributed information regarding the CDC Final Rule on Select Agents.
15. The next IBC meeting is scheduled for April 25, 2005, 2:30 PM in the UL Foundation building unless there are no proposals to review.
16. The meeting adjourned at approximately 11:40 am (motion by an IBC member, seconded by the University Safety Officer, motion passed).

Minutes of 8/31/05 UL Lafayette Institutional Biosafety Meeting

IBC members present: Walter Comeaux, Tom Pesacreta, Gus Gallo, Heather Gonsoulin, Patrice Frost, Paul Klerks. Also present: Ruth Landry (Office of Research and Sponsored Programs).

Excused: Don Ennis, Joey Pons, Tina Stefanski

1. The meeting was called to order at 11:15 a.m. The chair reviewed current committee membership, with a new IBC member replacing an IBC member. Later on during the meeting, the representative from the Research Office handed out a list of committee membership with contact information (Fax # for an IBC member was corrected).
2. Minutes of the last meeting (April 4) had been distributed prior to the meeting. There were no corrections or additions. The minutes were approved as distributed.
3. A listing was provided of all expedited reviews and renewals conducted since April 4th. One expedited review (BIOL05-03) and 5 renewals of projects that had not been modified from the original approved application and for which no adverse effects had occurred. All 6 applications had been approved.
4. Old business. (1) The changes to the application document, discussed at the 4/4 meeting, had been made to the document and were reviewed. An IBC member inquired about change in numbering (which was due to the addition of item #12 related to IACUC approval). A motion was made (by an IBC member, seconded by an IBC member) to officially approve the revised form. Motion passed (6-0). (2) Similarly, the changes to the Policy and Procedures document, discussed at the previous meeting, had been made by the chair and were reviewed. A motion was made (by an IBC member, seconded by an IBC member) to officially approve the new document. Motion carried (6-0). (3) Frequency of lab inspections was discussed at the previous meeting, deciding then on the wording "periodically and as needed". The chair felt that this was too vague and not providing any guidance to those doing inspections. Various options were discussed and it was felt that it would make most sense to use a fixed frequency and make this dependent on Biosafety level. A motion was made (by an IBC member, seconded by an IBC member) to do re-inspections yearly for those projects dealing with "Select Agents" and those at the "BSL3" level, while doing inspections once every two years for projects at lower Biosafety levels. This motion passed (6-0).
5. New Business. (1) The Chair brought up the issue of renewal for BIOL04-03, which is about to expire. This is a BSL3 / Select Agent project, but it has not yet started (the select agent arrived on campus today). The committee felt that a full review was needed for this renewal. (2). An IBC member suggested that

applications should not include a definitive starting date. Upon further discussion, it was felt that the currently used wording "Anticipated starting date" was appropriate.

6. Review of application NIRC05-02. (1) An IBC member asked about current procedures for monitoring suffering of primates. In response, An IBC member described current NIRC procedures. (2) An IBC member asked about procedures in the event of a hurricane. An IBC member discussed structural integrity of NIRC buildings and pre/post hurricane procedures. (3) The chair pointed out that the answer to question #28 on the application should be "BL3" instead of "BL2" in order for it to be consistent with the answer to question # 23 and with the ongoing procedures at NIRC for this type of work (BL3 practices in a BL2 facility). (4) An IBC member made a motion (seconded by another IBC member) for approval pending the change to question #28. Approved 6-0, with additionally a verbal approval by telephone from the BSO.
7. Meeting times were discussed. For this semester, meetings will be on the last Wednesday of the month, starting at 11 am. Next meeting will be September 28, 2005.
8. The meeting was adjourned at approximately 12 noon (by unanimous vote).

Minutes from 9/28/05 UL Lafayette Institutional Biosafety Meeting

IBC Members Present: Paul Klerks, Don Ennis, Heather Gonsoulin, Patrice Frost, Walter Comeaux, Gus Gallo, Tom Pesacreta. *Also Present:* Ruth Landry (Office of Research and Sponsored Programs)

Excused: Joey Pons, Tina Stefanski

1. The meeting was called to order at 11:10 am.
2. Minutes of the last meeting (August 31, 2005) had been distributed prior to the meeting. There were no corrections or additions from the membership. The minutes were approved as submitted.
3. Review of renewal application BIOL04-03. (1) The Chair brought up the renewal application for BIOL 04-03 submitted by the BSO, and circulated to the committee earlier. He indicated that the protocol was approved one year ago. (2) The PI reported that the BSL 2 level work was ongoing; however, the BSL 3 work had been on hold until all necessary approvals were secured. (3) The PI reported that he received his first batch of materials just a few weeks ago on August 31 via Fed Ex and indicated that Fed Ex had not followed proper protocol in delivery of the material. An IBC member recommended that a formal complaint be made to Fed Ex. After some discussion of the issue, the chair indicated that he would discuss making a written complaint with the University Safety Officer. (4) An IBC member inquired about procedures to be followed in case of inhalation. The PI indicated that a packet of medical and treatment information had been prepared and distributed to Lafayette General Hospital. Identical packets are available in a designated location in the lab. Should a lab worker or student suspect they have had contact with the subject material, they are instructed to take the packet and go to Lafayette General. He reviewed protective measures taken by all who work in the lab. (5) An IBC member inquired about procedures for handling disposables. The PI reported that the lab takes care of all disposables on their own by autoclaving immediately. (6) The committee inquired about treatment and follow up for suspected contact and the PI explained those processes and procedures. (7) An IBC member inquired if review of SOPs was done on a consistent and frequent basis. The PI assured that there are extensive SOPs available and they are reviewed regularly. (8) The chair asked that the Biosafety Officer leave the room so the committee could discuss and vote. (9) An IBC member made a motion (seconded by another IBC member) for approval emphasizing that the Biosafety Officer should be certain that all lab personnel are kept abreast of all relevant safety procedures. Approved 6-0.
4. Review of Application NIRC05-03. (1) The chair presented the subject application as submitted by a PI of NIRC; the application had been send to

committee members earlier. The chair informed the committee that the PI was not able to attend the meeting and asked an IBC member to provide a summary on her behalf. (2) An IBC member asked if this type of research had been done before. An IBC member explained some of the prior studies and how this protocol differed. (3) An IBC member reported that there is a vaccine for Hepatitis A that is available to all employees at NIRC. She made the recommendation that all employees working on the protocol be vaccinated. An IBC member concurred and added that even maintenance crews who work in the area be vaccinated as well. (4) An IBC member inquired why only two chimps were being used in the study. An IBC member explained that cost was a concern and that this was a preliminary study only. (5) An IBC member inquired if the PI considered using a species other than chimps. An IBC member explained the rationale for using chimps in this instance. (6) An IBC member (seconded by an IBC member) made a motion for approval with the addition that all employees working with the protocol are vaccinated for hepatitis A. Approved 7-0.

5. Summary of Expedited Reviews. The chair reported there had been none since the previous meeting.
6. Old Business. Nothing to report.
7. New Business. (1) The BSO reported that he would need to schedule an inspection at NIRC. An IBC member recommended that the BSO call the office to schedule a time. He indicated that he will provide NIRC with an inspection checklist for review and comment, specifically for assistance in checklist items particular to animal issues. (2) The chair reported that drills should be conducted annually, as required by the select agent final rules. He will work with the University Safety Officer to schedule such a drill. The BSO mentioned that the University Safety Officer discussed holding a tabletop to walk through the planned response of safety professionals in the community should an incident occur on campus.
8. The next meeting will be scheduled, tentatively, for Wednesday, October 26, 2005, at 11:00 am.
9. The meeting was adjourned at 12 noon by a unanimous vote.

Minutes
Institutional Biosafety Committee Meeting
December 19, 2005, 11:00 am

Members present: Dr. Walter Comeaux, Dr. Gus Gallo, Dr. Paul Klerks, Dr. Patrice Frost, Heather Gonsoulin, Joey Pons, Dr. Tina Stefanski. Also present: Ruth Landry (ORSP)

Excused: Dr. Tom Pesacreta, Dr. Don Ennis

1. The IBC Chair called the meeting to order at 11:10 am.
2. Minutes of the September 28, 2005 meeting had been distributed prior to the meeting and were addressed. An IBC member moved to change minute #4 where it was mentioned that the Hepatitis A is an *experimental* vaccine in the US; this is incorrect. The minutes, as distributed and with this one modification, were approved.
3. There was only one proposal for full review by the committee, application NIRC05-06. The PI was not able to attend the meeting. An IBC member described the contents of the proposal, which is similar to an earlier approved proposal by a PI at NIRC. An IBC member questioned whether an exact number (percentage) should be given for application question #18. The IBC Chair responded that the answer given on the application is acceptable, as it is below the crucial proportion ($2/3^{\text{rd}}$) relative to risk group classification. An IBC member moved that the proposal be accepted as written. An IBC member seconded the motion. The proposal was approved unanimously.
4. The IBC Chair discussed 3 expedited reviews conducted since the last IBC meeting. One was from the Biology department (involving test tube only research). The other 2 were from NIRC (both the same PI). Summaries of each of the three proposals were distributed.
5. Under the topic of old business, the IBC Chair indicated that documents associated with the IBC shall be maintained for 5 years. The representative from the Research Office indicated that this parallels with OSRP's other SOPs. The IBC Chair will be the custodian of these records. Also, with respect to old business, the University Safety Officer discussed a successful table top emergency drill recently conducted (12/15/05) with students working in the University's BSL-3 Select Agent facility.
6. Under the topic of new business, the IBC Chair indicated that the IBC might need a more in-depth understanding of the research done at NIRC. An IBC member commented that the IBC is getting a clearer picture of the IBC-related research at NIRC (initially somewhat less transparent due to our earlier application forms

being less explicit and due to the research that was ongoing at the time the IBC was reformed in 2004 being grandfathered-in to some extent). However, an IBC member also expressed a concern about NIRC employee safety. An IBC member and an IBC member described to the IBC some of the procedures and training that takes place with NIRC employees (e.g. pre-study meetings, annual job certifications, facility inspections, etc.).

7. An IBC member asked if minutes from the pre-study meetings could be provided to the IBC for review along with other documentation. An IBC member responded that if the IBC changes its procedures in this regard, it should do so throughout the campus, and not just for NIRC. The University Safety Manager reminded the committee that a very specific application is used to ensure the IBC that compliance is being met, which includes the PI's certification that the research will be conducted in accordance with all applicable regulations. The University Safety Manager also stated that in the application, the PI is required to cite the specific BMBL and/or NIH guideline that justify the appropriate level of risk.
8. The University Safety Manager suggested that perhaps the PI should be required to attend an IBC meeting in which a full review is required. An IBC member indicated that this could be a burden on many PIs. An IBC member further reminded the committee that it could always defer a vote on a proposal pending any clarifications from the PI regarding the research.
9. An IBC member asked the IBC if periodic reviews of the committee's actions could be done. The representative from the Research Office stated that she maintains a database of all proposals and will provide this at the next committee meeting. An IBC member also suggested that at the yearly review of a proposal, and/or during the yearly inspection of the applicable facility, the IBC should get a feel for where the project stands.
10. An IBC member asked about where basic Biosafety levels are decided for research. An IBC member responded that NIH Guidelines and BMBL regulations assist researchers in making this decision.
11. The IBC Chair suggested that during the Spring semester, the IBC could meet at NIRC and use that as an opportunity to take a tour of the facility.
12. The next IBC meeting will be scheduled for the last week of January (if any full reviews are to be conducted). The specific day and time will be determined after a review of the committee members' Spring 2006 semester schedules.
13. The meeting was adjourned at approximately 12:15 pm.