

PENNSTATE



Institutional Biosafety Committee

Date: April 17, 2006

From: William G. Greer, IBC Coordinator of Research Protections

To: Edward Hammond, Director of the Sunshine Project

Re: Penn State University's IBC meeting minutes

Dear Mr. Hammond,

Penn State's Biosafety Committee meets on an as needed basis. Please find enclosed the minutes of all Penn State University Institutional Biosafety Committee meetings held since May 1, 2003 as requested by the Sunshine Project.

Best Regards,

A handwritten signature in blue ink that reads 'William G. Greer'.

William G. Greer
Animal Care, Biosafety & Radioactive Materials
Office for Research Protections
The Pennsylvania State University
201 Kern Graduate Building
University Park, PA 16802

Telephone: 814-865-1775
Fax: 814-863-8699
email: wgg3@psu.edu

**OFFICE FOR REGULATORY COMPLIANCE (ORC)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
May 22, 2003**

Members Present: Aziz Ben-Jebria, Maurine Claver, Herbert Cole, Jeffery Dodds, William Greer, Charles Howsare, Teh-Hui Kao, Gretchen Kuldau, Jeffrey Peters, Curtis Speaker

Members Absent: Pamela Correll, Douglas Granger, Andrew Henderson, Laura C. Klein, Daniel Shaw
Andy Moore and Candice Yekel

Others Attending: Erica Kresovich

The meeting was called to order at 1:35 p.m. H. Cole presided as chair.

PREVIOUS MEETING MINUTES: No changes were noted to the March 4, 2003 meeting minutes; therefore, H. Cole motioned for full approval. Committee vote: 10 ayes, 0 nays, 0 abstentions

SUBCOMMITTEE ACTIVITIES: The Pathogen, rDNA and Carcinogen/Toxin subcommittee reports were made available to the Committee for their review. No comments were made from the Committee regarding these reports.

ATTACHMENT B: Letter from Rodney A. Erickson and Gary C. Shultz, *Safety and Security Procedures for Hazardous Materials and Food Processing*

On January 16, 2003, Rodney A. Erickson and Gary C. Schultz sent a letter to Robert Steele, Dean of the College of Agricultural Sciences, outlining the updates to University Safety Policy SY24 that pertains to the use of Biological Materials in Research and Instruction. The letter requested that Robert Steele submit a letter to Gary C. Schultz indicating that all departments under his authority are in compliance with the safety and security practices. The Committee reviewed the letter from Rodney A. Erickson and Gary C. Schultz regarding Safety and Security Procedures for Hazardous Materials and Food Processing. C. Speaker commented that University personnel are taking this issue seriously and that most users of Pathogens are also Isotope users and already have their storage areas and laboratory doors secured.

ATTACHMENT C: Draft of Policy IBC2A – “Oversight of Transgenic Mice Biohazards”

According to National Institutes of Health (NIH) regulations, the Institutional Biosafety Committee (IBC) should be reviewing all transgenic mice research protocols. Currently, the Institutional Animal Care and Use (IACUC) ensures that all federal regulations are being met. This draft proposes that if the use of transgenic mice, that are not shedding any viable virus or any hazardous proteins, is reviewed and approved by the IACUC, then the IBC will recognize the approval as compliance with those regulations that the IBC is expected to provide oversight for.

The Committee discussed the issue of disposal of transgenic mice. Currently, transgenic mice are fed to raptors at Shaver's Creek. Federal guidelines state that these mice cannot be fed to other animals unless approved by an appropriate agency. However, when contacted by W. Greer, no federal agencies stated approval to do this. However, NIH informed him that it is their internal policy not to allow their transgenic mice not to be fed to anything. The IBC is concerned that denying permission to feed these mice to the

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(cont'd)**

raptors, may drastically affect the budget of Shaver's Creek. Although, Shaver's Creek purchases most of their mice from another source, the transgenic mice are used to supplement what they already have. J. Peters suggested separating the mice, wild-type from transgenics, when disposing of them. This would still allow for some mice to be given to Shaver's Creek. H. Cole informed the Committee of his concern over ensuring that these mice are not going to put any of the raptors at risk of harmful disease. C. Speaker commented that these mice have been fed to the raptors for over 5 years now, and no health effects have been reported. J. Dodds stated that he believes that there really is no risk to giving these mice to Shaver's Creek, and that the intention of the guidelines was to prevent transgenic pigs from entering into human food. W. Greer stated that Penn State University recently received letter from the FDA regarding the situation of swine potentially getting into the human food chain at the University of Illinois. The FDA has decided to label rDNA as a new food animal drug for investigative use, which will now fall into FDA regulations and is covered by 21CFR. Presently, PSU does not work with genetically modified animals. If PSU ever decides to become involved in research involving food animals, they will take a closer look at these regulations at that time. None of the transgenic mice that PSU uses ever is rendered down for use in pet food, etc. The IBC decided that further investigation involving this issue is needed before a decision can be made regarding this. M. Claver suggested that W. Greer add to the policy a statement clarifying that this is both a IACUC and IBC policy. H. Cole made the following editorial changes to the draft of the policy; (1) page 2, under the heading titled Animal Containment, the word regulations was added to the end of the second sentence after the words Federal and State; (2) under the heading Animal Disposal, clarify the first sentence stating "As prescribed by NIH guidelines, dead or euthanized animals are disposed of accordingly", (3) clarify "that this policy only applies to policy defined transgenic mice" (meaning mice that are not shedding any viable virus or any hazardous proteins); (4) on page 1 under the heading Purpose, the word disposable was changed to disposal. W. Greer agreed to contact personnel at Shaver's Creek to determine exactly what effect not allowing transgenic mice to be given to them will have. W. Greer will also contact other Universities to see how they handle this issue. He will provide an update to the Committee at the next IBC meeting. H. Cole entertained a motion to approve the typed draft of the policy with the noted corrections. W. Greer motioned to approve. C. Speaker seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

ATTACHMENT D – Draft of Application for the Use of Pathogens in Classrooms

The purpose of this new application is to identify those pathogens that are being used and who is using the material. Also, to determine whether the IBC needs to review their proposed use of biohazardous materials in the course of classroom activities. Upon approval, a memo will be sent to University department heads informing them of this new application. W. Greer stated that he would like to implement this new application at the beginning of the Fall 2003 semester. The IBC decided to add an additional question, (#6) asking if the investigator has sought out any alternatives other than the biohazardous material that they propose to use. G. Kuldau commented that the course number should be added to the top of the application and location where the class will be held. Also, the IBC would like a statement added to the application stating that all persons (investigators, teaching assistants) involved in the course be listed on each protocol. W. Greer will make the suggested changes and e-mail the updated version to the IBC for review and approval. The Committee decided that teaching protocols are to be reviewed by W. Greer and C. Speaker, and if necessary, they will bring it to the attention of the full Committee. W. Greer will revise the draft of this application and forward it to the Committee for review and comments. A vote will be taken at the next IBC meeting.

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ATTACHMENT E: - Draft of Application for the Use of Human Biologics in Classrooms

A few changes were noted to the application, (1) question # 6, the word "protection" was changed to "protective", (2) question numbers 6 and 7 are to be reversed, (3) the word "personalized" will be deleted from question # 7, (4) question #6, blood borne was changed to bloodborne , (5) question #6, the second sentence was deleted. (6) The Committee also decided to add an additional question, #8 that reads, "Please provide an example of your course syllabus demonstrating the inclusion of training and personal protective equipment". W. Greer motioned to approve the draft as corrected. M. Claver seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

ATTACHMENT F: - Draft of Application for the Use of Human Biologics in Research

W. Greer informed the IBC that he has been receiving complaints from investigators stating that the Application for the Use of Biohazardous Materials is too lengthy. In the past, everything was incorporated into one application for the upcoming implementation of electronic submissions. However, it could take up to one (1) year to begin the process. The intention of this application is to review the use of human blood, blood products, human body fluids, and /or human tissues. C. Speaker stated that all of these applications can be forwarded to him since he handles all of the bloodborne training for the University. He would also like the statement at the top of the first page of the application to be revised to read, "IF ANY SAMPLES ARE KNOWN OR SUSPECTED TO BE CONTAMINATED WITH INFECTIOUS AGENTS, A RESEARCH APPLICATION MUST BE SUBMITTED TO THE IBC FOR REVIEW". J. Dodds stated that he would like question #3 deleted from the Application in an effort to reduce writing and application completion time. The IBC agreed to this deletion. Also, the words "course title" were deleted from the top of the first page of the application. This policy will be reviewed internally by the Office for Research Protections and C. Speaker. If need be, the application will be forwarded to the full IBC. H. Cole motioned to approve this policy. M. Claver seconded the motion. Committee vote 10 ayes; 0 nays; 0 abstentions.

COMPLIANCE COORDINATOR'S REPORT:

Animal/Biosafety Protocol –

W. Greer raised for discussion the topic of the Animal/Biosafety Protocol. Currently, policy SY24 states that a Biohazard is being used in conjunction with animals, the Principal Investigator must submit an Animal/Biosafety Protocol. These protocols are to be posted on laboratory entrances so that the animal caretakers are aware of the particular biohazardous material that may be contained in the animals of that room. The IBC decided that a question regarding the use of Biohazardous Materials needs to be added to the IACUC (Institutional Animal Care and Use Committee) Application, to clarify this issue. The question will state, "Are the materials that you are using in conjunction with animals biohazardous? If the material being used poses a hazard, an Animal/Biosafety protocol must be completed. If it is not a biohazard, the Principal Investigator must state why it is not. It is then up to the IBC to determine if the material poses a hazard. Causing an additional occupational health hazard. If there is no risk posed, the Principal Investigator must prove this with substantial evidence. After discussion of this topic, the Committee agreed that J. Dodds, H. Cole, W. Greer and C. Speaker will work together to establish a draft flow chart for discussion of this topic at the next IBC meeting.

BIOSAFETY OFFICER'S REPORT:

C. Speaker is planning to develop an online Biosafety training program this summer. This online quiz will focus on the major components under each Biosafety level such as personal hygiene, work practices, laboratory facility features and building features. He will also be encouraging Teaching Assistants to integrate safety information into their course syllabus. C. Speaker is also going to be updating those persons on campus who are working with Select Agents regarding security measures, disposal options, etc. He is concerned that research involving these materials will increase, and he wants to ensure that the University and the IBC are prepared.

FYI – This was H. Cole's last meeting as IBC Chair, his term has ended.

The next scheduled meeting is scheduled for Tuesday, July 1, 2003 at 1:30 pm in room 201 of the Kern Graduate Building.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

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August 5, 2003**

Members Present: Aziz Ben-Jebria, Jeffery Dodds, William Greer, Charles Howsare, Teh-Hui Kao, Gretchen Kulda, Carlton Miller, Elaine Schuckers, Daniel Shaw, Curtis Speaker

Members Absent: Maurine Claver, Herbert Cole, Pamela Correll, Douglas Granger, Andrew Henderson, Laura Klein, Jeffrey Peters and Candice Yekel

Others Attending: Erica Kresovich

The meeting was called to order at 1:34 pm. Daniel Shaw presided as Chair.

The Institutional Biosafety Committee (IBC) welcomed new IBC Chair, Daniel Shaw.

Previous Meeting's Minutes:

A few changes were noted to the May 22, 2003 IBC meeting minutes. (1) on page 2, in the first paragraph, the sentence "Presently, PSU does not work with food animals" was changed to state, "Presently, PSU does not work with genetically modified animals." The minutes were approved contingent on this change. C. Howsare motioned to approve the minutes; C. Speaker seconded the motion. Committee vote: 9 Ayes; 0 Nays; 0 Abstentions.

Subcommittee Activity Reports:

The IBC reviewed the subcommittee reports that were handed out at the meeting. No changes were noted to the reports. C. Speaker reminded the IBC that they previously decided on parallel reviews. For example, if a Biohazardous research protocol involves recombinant DNA and pathogens, a member of each of those respective subcommittees must review the protocol. The IBC also suggested that these reports be included in the monthly meeting packets so that the Committee members would have sufficient time to review them and bring any comments/questions to the meetings. Additionally, page numbers will begin to be added to these reports. The reports were approved contingent upon these changes.

NEW BUSINESS

Animal/Biohazard Safety Protocol:

The last page of the IACUC Application was distributed to the IBC to demonstrate changes that have been made regarding the issue of Animal/Biohazard Safety Protocols. A new question was added to the application that states, "Will the animals, caging, or bedding materials be contaminated with hazardous materials that will pose a risk to personnel caring for or working with the animals?" The reasoning is the investigators are likely to be more aware of whether hazards (as defined by Penn State Policy, SY-24) pose a risk to animal caretakers. Compliance Coordinator, W. Greer when a new IACUC application is received, will initially review the investigators response. If further review is needed, he will forward the issue to the appropriate subcommittee member of the IBC. Also, the IBC suggested that the following statement be added to the IBC reviewer ballot, "Does the use of this in animals pose a risk to humans caring for these animals?"

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Letter from Jeffrey Peters, IBC member:

Dr. Jeffrey Peters suggested in a memo to W. Greer (dated July 24, 2003) that the IBC require Principal Investigator's to include a MSDS for hazardous substances (as part of their IBC application) they intend to use as part of their research activities. In addition, they should be required to indicate whether the concentration of the hazard poses a negligible, slight, moderate or great risk, based on an LD₅₀ or other reasonable marker of toxicity, to those potentially exposed. The LD₅₀ or other form of reasonable marker should be clearly marked in the application. The IBC unanimously agreed to implement these questions into the Application for the Use of Biohazardous Materials.

Peripheral Hazards Associated with Various Research Projects (e.g. Rabies, Schistosomiasis, Haunta Virus):

W. Greer, IBC Compliance Coordinator, urged the committee that a systematic approach be developed for evaluating the level of risk student researchers are exposed to as part of the peripheral hazards to research activities. For example some investigators could be potentially exposed to agents such as rabies, haunta virus, Schistosomiasis and Lyme disease as they conduct their research. William Greer spoke to University attorneys regarding this issue and they stated that as long as students of PSU are involved, the University is responsible for not exposing them to a know hazardous situation. Dr. Pell, the Vice President for Research stands firmly behind the notion that the University will not knowingly put students into a potentially hazardous situation. C. Howsare, W. Greer, and C. Speaker are scheduled to meet before the next scheduled IBC meeting to discuss risk assessments and will bring some materials and data to the meeting to present to the IBC. The IBC agreed that they are going to table discussion on this topic until the next IBC meeting.

Requests have been made to allow graduate students to participate in research activities that are known to have peripheral risks. The thought is to develop a system that will evaluate the degree of risk associated with each research activity and make recommendations accordingly.

Compliance Coordinator's Report:

At the last IBC meeting, the Committee approved the new teaching applications for the use of pathogens and blood in laboratories. W. Greer informed the IBC that to date, the Office for Research Protections has not received any of these applications, and has had only one request for information regarding this new application. He solicited comments from the IBC in regards as to how to handle this situation. C. Speaker suggested contacting Phil Moore, the head instructor of the Biochemistry and Molecular Biology Department, which contains a large portion of these users. He also stated that due to the fact that this letter was sent out in the middle of the summer, when most faculty are not on campus, may be a factor. The IBC decided that W. Greer should contact via e-mail or telephone, individuals whose focus in these areas.

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Biosafety Officer's Report:

- C. Speaker informed the IBC that another PSU faculty member, Dr. June Liu from the Biology Department, is using a material on the Select Agent list. Dr. Liu previously contacted C. Speaker to inform him that she is interested in purchasing a small amount (1mg) of Tetrodotoxin, which is a toxin derived from Puffer Fish. C. Speaker has already met with Dr. Liu to discuss her method of handling and storage the material.
- C. Speaker stated that Maurine Claver, Director of Environmental Health and Safety, to draft all of the necessary paperwork for the University to register as an entity to work with Select Agents. This is a precautionary step in preparation for Investigators who wish to work with either a toxin above the exemption level or a viable agent such as a virus or bacteria. C. Speaker does not want the IBC to become an impediment to Investigators, which is why he is beginning this process before this occurs. He will be drafting plans for security of the agent, cyber security, personnel accountability and reliability, shipping of the materials into the University, disposal of the material, emergency operations, etc.
- C. Speaker also informed the IBC that there is discussion occurring among his colleagues regarding the issue of Human Cell Lines in research. Many of his peers believe in the notion that persons working with Human Cell Lines should be subject to the Bloodborne pathogen requirements. OSHA is also leaning towards this idea as well. Although, C. Speaker does not necessarily agree with this statement, he wished to inform the IBC of this thought that is occurring among his professional peers.

The meeting was adjourned at 2:47 p.m.

The next scheduled meeting is scheduled for Tuesday, September 16, 2003 at 1:30 pm in room 201 of the Kern Graduate Building.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

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201 Kern Graduate Building
October 7, 2003**

Members Present: Maurine Claver, Herbert Cole, Jeffery Dodds, William Greer, Charles Howsare, Teh-Hui Kao, Gretchen Kulda, Carlton Miller, Daniel Shaw, Elaine Schuckers, Curtis Speaker

Members Absent: Aziz Ben-Jebria, Pamela Correll, Douglas Granger, Laura Klein, Jeffrey Peters, Candice Yekel

Others Attending: E. Kresovich

The meeting was called to order at 1:34 pm. Daniel Shaw presided as Chair.

Previous Meeting's Minutes (August 5, 2003):

One change was noted to the previous meeting minutes. William Greer was listed as absent, when in fact he was present. E. Kresovich will correct the minutes to reflect this. The minutes stand approved as corrected. Committee vote: 11 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports:

The Committee reviewed the previously distributed sub-committee activity reports. The following changes were noted to the reports: Andrea Mastro, IBC# 16371 titled, "Trafficking of Metastatic Breast Cancer Cells in Bone" was changed from a BL-2 to a BL-1; Gary Moorman, IBC# 16424 titled, "Pythium Species and Population Identification and Epidemiology Using DNA Markers" was changed from a BL-1 to a BL-2. C. Howsare expressed his concerns to the Committee regarding overexposures of carbon tetrachloride and arsenate and arsenite and exposure to feces in Jeffrey Peters protocol # 16502, "PPARB-null Mice to Assess Mechanisms of Liver Toxicity". J. Dodds informed the Committee that the ARP (Animal Resource Program) requires investigators to complete the Animal/Biohazard Form which outlines procedures that investigators are going to use for such things as cleaning cages and assured the Committee that J. Peters has experience working with these materials and will take the necessary safety precautions while working with them. E. Schuckers questioned why the use of nasal masks was left to the discretion of the PI. C. Speaker noted that the IBC doesn't usually leave the discretion of the use of nasal masks, but that he was more concerned that this protocol was reviewed by a rDNA subcommittee member when it really does not involve any recombinant DNA work. He is using transgenic mice which is considered rDNA by the IBC, and requires review by the IBC. C. Speaker agreed to meet with J. Peters to review the personal protective equipment (PPE). He will provide a summary of this meeting to the IBC at the next scheduled meeting. M. Claver asked why J. Peters' IBC # 14870 was also reviewed by a member of the rDNA committee. W. Greer, IBC Compliance Coordinator, informed the Committee that he designates the reviewer based on the questions that the principal investigator answers on the application. C. Speaker stated that the IBC members need to be more aware of what they are reviewing to ensure that they are reviewing each protocol for the correct sub-committee.

The sub-committee reports were approved contingent upon the above mentioned changes. Committee vote: 11 ayes; 0 nays; 0 abstentions.

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OTHER BUSINESS

Formal Risk Assessments:

C. Howsare, C. Speaker and W. Greer have met several times to discuss formal risk assessments. The goal is to develop a more quantitative method of risk assessment that will clearly review risks associated with the research protocol as well as the environmental/peripheral hazards. The discussion of this topic led to the example of Dr. Jay Stauffer's ongoing research with Cichlids in Lake Malawi, Africa. Previously, Jay Stauffer requested that the IBC permit him to take Penn State graduate students to Africa to participate in the Cichlid study. Schistosomes, a highly infectious protozoa occur naturally in Lake Malawi and are an ancillary hazard of Dr. Stauffer's research. The IBC denied approval for Dr. Stauffer to involve graduate students in the study. This decision was based on risks associated with peripheral hazards. Dr. Stauffer's concern is that many peripheral hazards associated with other research protocols are of equivalent risk for example rabies and Lyme disease. The IBC realizes a more formal risk assessment tool is needed to adequately review research protocols. C. Howsare, W. Greer and C. Speaker will continue to work on the development of a risk assessment guide to aide in the review of Biohazardous Materials research projects.

Compliance Coordinator's Report:

Teaching Applications – Update

In September 2003, at the beginning of the fall semester, the IBC implemented two (2) new Applications for the Use of Biohazardous Materials. One application is for the use of human blood or products for Teaching purposes, the other is for the use of human blood or products for Research purposes. W. Greer commented that only a few of these applications were received for review. C. Speaker stated that he would contact Chris Maricondi, the head of the Science division for the Commonwealth Colleges and Phil Moore regarding the status of submitting teaching applications. Another point of concern for the IBC is using Pathogens in undergraduate elementary microbiology classes. For elementary microbiology classes, pathogens use should be limited to demonstration only, if at all possible. This will provide the student with a more ample amount of time to become comfortable working in a lab setting, thus, helping to prevent certain problems that may arise. C. Speaker informed the IBC that Phillip Mohr, Department Head of Biochemistry and Molecular Biology, agrees with the idea of reducing the potential risks of undergraduate students that are working with Pathogens by implementing the measures of limiting their hands on experience until later into the semester. The IBC suggests that another letter and/or e-mail be sent to the personnel who teach these courses and/or work with these materials. C. Speaker agreed to meet with Chris Maricondi before this letter/e-mail is sent to discuss the most useful approach. C. Speaker will update the IBC on this matter at the next scheduled meeting.

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Biosafety Officer's Report:

C. Speaker informed the IBC that he and M. Claver have been meeting regularly to create a comprehensive Select Agent program package to address all significant issues regarding this topic such as the regulations, laboratories, emergency procedures, safety issues, etc. C. Speaker has also put together a Power Point presentation that he would like to show to the IBC at the next meeting for feedback before he releases it onto Angel (Penn State's online teaching resource) for training purposes.

FYI-

C. Howsare informed the IBC that PITT (the University of Pittsburgh) has just received \$18 Million dollars to create a Biosafety Level 3 facility to conduct Bio-Terrorism research.

The meeting adjourned at 2:41 p.m.

The next scheduled meeting for Tuesday, November 4, 2003 has been cancelled. The IBC will meet again December 2, 2003 at 1:30 pm in 201 Kern Graduate Building.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

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INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
December 9, 2003**

Members Present: J. Dodds, W. Greer, C. Howsare, T. Hui-Kao, G. Kuldau, D. Shaw, C. Speaker

Members Absent: A. Ben-Jebria, M. Claver, H. Cole, P. Correll, D. Granger, A. Henderson, L. Klein, C. Miller, J. Peters, E. Schuckers.

Others Attending: E. Kresovich

The meeting was called to order at 1:40 pm. Daniel Shaw presided as Chair.

Previous Meeting's Minutes (October 7, 2003)(Attachment A):

One change was noted to the October 7, 2003 meeting minutes by J. Dodds; on page 1 under the paragraph Subcommittee Activity Reports, the following sentence "He is using transgenic mice which is not considered rDNA by the IBC" was changed to "He is using transgenic mice which is considered rDNA by the IBC, and requires review by the IBC". The minutes were approved contingent upon this change. C. Howsare motioned for approval. G. Kuldau seconded the motion. Committee vote: 7 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (Attachment B):

- **IBC# 14611 -**
J. Dodds questioned the IBC regarding Ramachandran's research protocol # 14611. He stated that typically when a Principal Investigator is using rDNA with animals, they are responsible for showing that the vector is not replication competent, however, he is unsure of exactly how one proves this to be true. C. Speaker stated that Stratagene sells a kit that is replication deficient and also, sometimes, companies assure that their materials are replication incompetent.
- **IBC # 15641 -**
W. Greer asked the IBC if Wendy Trigona will be permitted to assume all responsibilities of Dr. Lorraine Sordillo's project once Dr. Sordillo leaves PSU in February 2004. The IBC asked that W. Greer provide additional information such as Wendy Trigona's status (Graduate student, PostDoc, etc.,) and determine if she is just helping to finish the project or if she will in fact be continuing once Dr. Sordillo has left. W. Greer agreed to follow-up and will provide the IBC with an update of this situation at the next scheduled IBC meeting.

NEW BUSINESS:

Policy IBC 1A

The main purpose of this policy is to obtain better control of Pathogen use in laboratories. C. Speaker is planning on contacting Chris Maricondi, head of Science curriculum for the Commonwealth Colleges to discuss this new policy. The major goal of this policy is to reduce the utilization of Pathogens in undergraduate research laboratories. The IBC's main questions to Faculty are: (1) Is work being done as a demonstration so that the students can view procedures, or are the students actually handling the pathogens themselves? If the students are doing the hands-on work themselves, the IBC is encouraging faculty to wait until the latter part of the semester to provide access of these pathogens to the students to ensure a better understanding and comfort level of aseptic techniques and also to reduce the risk of accidental infection. Another suggestion would be to allow the students to conduct the work but by using a non-hazardous material.

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Annual Review of IBC Applications –

The IBC reviewed and approved all IBC Applications for use until December 31, 2004. Committee vote: 7 ayes; 0 nays; 0 abstentions.

The only application that was changed is the Application for the Use of Biohazardous Application (Research). The following changes were noted: (1) the questions under number 3 were changed to include check boxes; (2) question 3A is replacing question number 5; (3) question 3B is replacing question number 8; (4) under question 3C, the select agents list was deleted from the application and a hotlink to the CDC's website where the current select agent list is located was added; (5) question 3D was modified to include a link to questions 4, 5 and 6 on the application for the use human blood, fluids and/or tissues; (6) questions 3F and 3G were changed to specifically refer to those carcinogens and toxins used in conjunction with animals; (7) question number 6 was modified to read, "Please list the pathogens that will be utilized"; (8) in question 3H, transgenic animals was deleted from the question and a statement regarding only transgenic plants that are commercially available was added; (9) the IBC inquired why the application is seeking information regarding APHIS permits? C. Speaker will speak with Maurine Claver to discuss exactly why and if this question needs to remain on the application. C. Speaker will provide an update on this issue at the next scheduled meeting.

Committee member J. Dodds raised the question of why an Investigator that has multiple IACUC (Institutional Animal Care and Use Committee) protocols, needs to submit a separate IBC protocol for each corresponding IACUC protocol. He argued that if they have been approved to utilize the material, why then do they need to submit a separate IBC for each corresponding IACUC protocol. W. Greer informed the committee that they previously voted upon and agreed to this change. Faculty and Graduate students were contacted in January of 2003 to inform them of this change. This change was made because of conflicting approval periods. For example, in the past instances have occurred where an IBC protocol expired before it's corresponding IACUC protocol. Investigators were contacted and informed of this and were requested to submit another IBC protocol to cover their work. Many times this did not occur, thus, resulting in research being conducted without the proper approval from both Committees. The Office for Research Protections has found that mandating that a separate IBC application be submitted for each IACUC and/or IRB protocol that is using Biohazardous materials, is more manageable for both the investigator and research processes. C. Speaker suggested adding a question to the applications stating, "Is this the same or similar to research that you are currently conducting at Penn State?" If the answer is yes, then the Investigator will need to provide the approved title and/or IBC number. Members of the IBC can then review these applications in an expedited manner since the work and materials are already approved. After discussion of this topic, W. Greer asked the IBC, "Do we continue to ask for multiple IBC submissions for corresponding IACUC and/or IRB protocols?" W. Greer agreed to speak with IRB administrators regarding this issue.

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Annual Review of IBC Policies (Attachments C and D):

Attachment C: Policy IBC1A – Handling Human Blood, Tissue or Fluids

Attachment D: Policy IBC2A – Oversight of Transgenic Mice Biohazards

One change was noted to Attachment C. Number 3 on page 2, should read Universal precautions. After review of these policies the IBC unanimously voted to renew approval for both of these policies. Committee vote: 7 ayes; 0 nays; 0 abstentions.

COMPLIANCE COORDINATORS REPORT:

Compliance Coordinator, W. Greer informed the IBC that beginning January 2004, the Office for Research Protections is now ready to implement Annual Reviews being submitted electronically, via e-mail to Erica Kresovich, emk128@psu.edu. If this works well, the ORP will then move on to receiving new applications electronically as well.

BIOSAFETY OFFICER'S REPORT:

C. Speaker, University Biosafety Officer, prepared a training program (Power Point presentation) titled, "*Biological Safety: Principles and Practices*". He presented this to the IBC for comments and review. He provided a handout for the IBC members to follow. The target audience for this presentation is laboratory technicians and first year graduate students. A copy of this handout is included in the December 9, 2003 IBC meeting packet on file in the 2003 IBC records in the Office for Research Protections.

J. Dodds motioned to adjourn the meeting. W. Greer seconded the motion.
The meeting adjourned at 2:52 p.m.

The next meeting is scheduled for February 3, 2004.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
March 3, 2004**

Members Present: Aziz Ben-Jebria, Jeffery Dodds, Maurine Claver, Herbert Cole, William Greer, Teh-Hui Kao, Carlton Miller, Jeffrey Peters, Curtis Speaker

Members Absent: Pamela Correll, Douglas Granger, Andrew Henderson, Charles Howsare, Laura Klein, Gretchen Kulda, Daniel Shaw, Elaine Shuckers

Others Attending: E. Kresovich, Jacqueline Gardner

The meeting was called to order at 10:02 am. Herbert Cole presided as Chair in Daniel Shaw's absence.

Herbert Cole introduced and welcomed the Office for Research Protection's new Associate Director, Jackie Gardner to the IBC.

Previous Meeting's Minutes (December 9, 2003)(Attachment A):

One change was noted to the December 9, 2003 meeting minutes. It was motioned that the following sentence be revised; "He is using transgenic mice which is not considered rDNA by the IBC, but still requires review" was changed to "He is using transgenic mice which is considered rDNA by the IBC and was reviewed according to the IBC's policy for reviewing applications involving transgenic mice." The minutes were unanimously approved by the IBC contingent upon this change. Committee vote: 9 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (Attachment B):

W. Greer, IBC Compliance Coordinator, noted that his reviewer comments did not appear on the report list. E. Kresovich agreed to check to ensure that his comments were in fact in PRAMS.

The Subcommittee Activity Reports were unanimously approved by the IBC. Committee vote: 9 ayes; 0 nays; 0 abstentions.

New Business:

Full committee review of Dr. Bhushan Jayarao's IBC Protocol # 18085, "Evaluation of a novel plant-based *Clostridium perfringens* vaccine using a mouse model"

Dr. Narasimha Hegde and Dr. Mary Kennett attended this meeting to provide answers to the IBC's questions and/or concerns regarding Dr. Jayarao's submission request to use Biohazardous materials. Drs. Hegde and Kennett are Co-Investigators on this research protocol and attended this meeting on behalf of Dr. Jayarao.

Dr. Hegde explained the purpose and methods of this research protocol. The IBC members posed questions regarding the toxicity of the materials, the containment of the genetically modified Arabidopsis plants and characteristics of the gene constructs. After discussion, the IBC agreed that Dr. Jayarao should resubmit the application with the following modifications:

- Since the PI has indicated the plants will not be producing the perfringens toxin, question 3(g) on the application should not be marked yes. The PI should also supply references to substantiate the claim that the constructs will produce no active toxins.

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INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
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(CONT'D)**

- A copy of the Animal/Biohazard Safety form should be submitted with the application
- Provide the security measures that will be followed to contain the genetically modified plants to include containment in growth chambers with a plastic covers
- Provide additional information on the vector and host to be used for gene expressions

Committee vote: 9 ayes; 0 nays; 0 abstentions.

Risk Assessment Update:

W. Greer informed the IBC of the status of this project. He indicated that he, Curtis Speaker and Dr. Charles Howsare have been working together to created standard SOP's for conducting a Risk Assessment. Curtis Speaker stated that their goal is to formalize a Risk Assessment Program. Ideally the program will provide a method for quantifying the risks in an attempt to provide a method for systematically making decisions rather than basing them totally on the committee member's opinions.

COMPLIANCE COORDINATORS REPORT:

The committee was updated on the status of Wendy Trigona who has assumed the supervisory responsibilities in Dr. Lorraine Sordillo's laboratory. Dr. Sordillo left Penn State for a position at Michigan State University. Wendy Trigona is a Graduate Student at Penn State University who has been working with Dr. Sordillo prior to her departure from the university. According to University policy, Graduate Students can be the principle investigator on Biohazardous materials research protocols.

It was suggested that many IBC applications are being submitted without enough detail and committee members are unable to conduct an adequate review. Question #1 on the application states, "What is the purpose of this study?" The committee agreed question 1 should be revised to read as follows: "What is the purpose of this study (Please provide a detailed description of the planned research activities and how they will be conducted)?" in hopes more detail will be provided for reviewers.

The IBC also decided to add the following to question 3(a) the following statement; **"Please complete the Animal/Biohazard Safety protocol and include it with your application. This form can be accessed at: <http://www.research.psu.edu/orp/BIO/app/animal%20bio.rtf>**

In addition, the IBC decided to revise question #4 on the research application to clarify requests for wher biohazardous materials will be used and stored. It was revised to differentiate between laboratories, animal husbandry rooms and storage locations.

Jeffrey Peters motioned for approval. Jeffery Dodds seconded the motion. The IBC unanimously approved the motion to approve the revisions and additions of this question.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
March 3, 2004**

BIOSAFETY OFFICER'S REPORT:

Updates:

- Curtis Speaker informed the IBC that Dr. Douglas Granger is reestablishing his laboratory to room 110 in Health and Human Development East in an attempt to further separate his University laboratory from Salimetrics, which is located in 302 Lubert Building.
- Environmental Health and Safety recently hired Dale Stehley as the University's Hazardous Materials Shipping specialist. He will be overseeing all University shipments of hazardous materials including those from the Applied Research Laboratory and the Animal Diagnostic Laboratory.
- Select Agent Update: Curtis Speaker is continuing to work on developing the Select Agent program at Penn State University. He is working to have the program ready in anticipation of faculty members who will want to work with these materials in the future. He is currently working on the human resources and personnel end of things as well as physical security required for laboratories that involve this work. The CDC audited Hershey Medical Center's Select Agent Program on Feb. 10, 2004. Two weeks prior to this audit, Curt Speaker conducted a mock audit of their Select Agent Program to aid in preparation of the arrival of the CDC. This audit was very helpful to Hershey Medical Center and also very useful to Curt, as he will be conducting these audits at other campus locations when research involving Select Agents takes place. Once this program description is complete, Curt will make the select agent program available to the IBC for their review and approval at a future meeting.

The meeting adjourned at 11:08 am.

The next meeting is scheduled for April 7, 2004.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
May 5, 2004**

Members Present: Abdelaziz Ben-Jebria, Herbert Cole, Jeffery Dodds, William Greer, Charles Howsare, Gretchen Kulda, Jeffrey Peters, Daniel Shaw, Elaine Shuckers (Community Member), Curtis Speaker

Members Absent: Maurine Claver, Pamela Correll, Douglas Granger, Andrew Henderson, Teh-Hui Kao, Laura Klein, Carlton Miller (Community Member), Candice Yekel

Others Attending: Jacqueline Gardner and Erica Kresovich

The meeting was called to order at 10:06 am. Daniel Shaw presided as Chair.

Previous Meeting's Minutes (March 3, 2004) (Attachment A):

No changes were noted to the March 3, 2004 meeting minutes; therefore, H. Cole motioned for full approval. G. Kulda seconded the motion. Committee vote: 10 ayes, 0 nays, 0 abstentions.

Subcommittee Activity Reports (Attachment B):

The IBC reviewed the subcommittee activity reports.

During the subcommittee activity reports a discussion regarding the use of carcinogens in animals was initiated. In an attempt to minimize the volume of paperwork required by principle investigators, the IBC entertained the motion that animal researchers using carcinogens at low doses or chemical with minimal carcinogenic properties should not be required to submit to the IBC. After discussion, the IBC concluded they would not change current policy (SY-24, "The Use of Biohazardous Materials in Research and Instruction") and continue to require submission of research activities any carcinogens in conjunction with animals. As policy denotes, if the carcinogen is ancillary to the research, then submission to the IBC is not necessary. For example if an investigator proposed preserving animal tissue samples in formaldehyde, submission to the IBC would not be required. Also noted was when principal investigators indicate on an IACUC application that they are going to use carcinogens, they are directed to complete an IBC submission. The discretion as to whether a chemical is potentially carcinogenic, is left to the discretion of the principal investigator.

No changes were noted to the subcommittee reports; therefore approval was unanimous.

Committee vote: 10 ayes; 0 nays; 0 abstentions.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
May 5, 2004
(CONT'D)**

NEW BUSINESS/ COMPLIANCE COORDINATORS REPORT:

IBC submission and protocol review process update:

W. Greer, IBC Compliance Coordinator informed the IBC that the number of submissions (New Applications, Modifications and Annual Reviews of existing approved research protocols) is steadily increasing. In 2002, there were 162 submissions and in 2003 there were 301 submissions. The projected number of submissions for 2004 is 400 – 450. He indicated that the next step in PRAMS (Protocol Review and Approval Management System) development is to initiate the electronic application submission and review process. The IBC can expect this phase to begin by late fall of 2004.

IBC approval number required prior to releasing awarded funds:

The IBC was informed that prior to an investigator establishing a budget from grant precedes ORP must provide an approved IBC protocol number to PSU financial offices. With the implementation of this process, it has been noted that many investigators conducting research with rDNA have determined their study to be exempt from review under the NIH regulations and subsequently not submitted to the IBC. With this, establishing of budgets has been delayed because approved IBC numbers are not available. The IBC historically has asked investigators to submit all proposed use of rDNA to the IBC for review. If a project were determined to be exempt by the IBC reviewer, the committee would register the submission as permanent records.

The question was proposed should the IBC, without intervention, permit investigators to make the determination whether their study is exempt under the NIH guidelines? The principle deterrent is if an investigator inadvertently makes an incorrect determination it could potentially jeopardize PSU funding from the NIH. After discussion, the IBC decided the following; (1) W. Greer will continue to all contact principal investigators working with rDNA and require an IBC submission; (2) he will contact other institutions of higher education to inquire how they handle “exempt” rDNA research; (3) he will also talk with Penn State University attorneys to discuss the possibility of investigators assuming the responsibility of their decision by signing a memo indicating their study is exempt from IBC review, (4) and a memo will be drafted to Department Heads/Research Deans informing them that all research involving rDNA should be submitted to the IBC for review (the content of this memo may be determined at the June 2 IBC meeting). The IBC agreed to table this discussion until the next IBC meeting on June 2, 2004.

To help with this issue in the meantime, the IBC voted to recommend to Environmental Health and Safety that the following statement be removed from Definition #5 of Penn State Policy SY-24 that reads, “unless exempted by National Institutes of Health Guidelines”. H. Cole motioned for approval. E. Shuckers seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

Working with concentrated levels of BL-1 Organisms:

The IBC was informed a PSU Faculty member submitted an IACUC research application requesting to inject fish with a BL-1 organism. The bacteria were concentrated for the purpose of determining a LD50. The question posed to the committee was since our current policy only requires review of those organisms at BL-2 level and above should the committee consider the concentration of the organism (BL-1) when deciding if a project should be submitted for review. The committee agreed the concentration of the organism is irrelevant and that non-pathogenic organisms are not expected to cause disease in healthy adults, therefore in accordance with SY-24 it was agreed that no submission should be required.

BIOSAFETY OFFICER'S REPORT:

C. Speaker informed the IBC that there is a self-appointed watchdog organization called the Sunshine Project. This organization is faxing over 400 Institutional Biosafety Committees around the county requesting copies of the minutes of their last two (2) months IBC meeting (NIH guidelines state that IBC meeting minutes be available to the public). To date, about 50 percent those contacted have responded. Currently, on "Sunshine's" website, they indicate that Penn State University has not responded to their requests for information. However, no one (The Vice President for Research or the Office for Research Protections) to date has received this request. Just recently, this group has asked the NIH to suspend federal funding to institutions that have major biotechnology contracts with NIH (Penn State is not one of these institutions) because they have not responded to this letter. Candice Yekel, Director, Office for Research Protections, has decided to forward a copy of the memo to University lawyers and ask for legal advice.

The meeting adjourned at 11:23 am.

The next meeting is scheduled for June 2, 2004.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
June 2, 2004**

Members Present: M. Claver, H. Cole, J. Dodds, W. Greer, C. Howsare, C. Miller, J. Peters, E. Schuckers, D. Shaw

Members Absent: A. Ben-Jebria, P. Correll, D. Granger, A. Henderson, L. Klein, G. Kuldau, C. Speaker, C. Yekel

Others Attending: Jacqueline Gardner and Erica Kresovich

The meeting was called to order at 10:01 am. D. Shaw presided as Chair.

Previous Meeting's Minutes (May 5, 2004) (Attachment A):

It was noted that the start time for the May 5, 2004 IBC meeting minutes needs changed from 11:06 am to 10:06 am. The meeting minutes were unanimously approved contingent upon this change.
Committee vote: 9 ayes, 0 nays, 0 abstentions.

Subcommittee Activity Reports (April 26, 2004 – May 17, 2004) Attachment B):

The IBC reviewed and approved the subcommittee activity reports. One change was noted to the details of IBC# 18626, "Molecular Interactions Between Insects and Pathogens/Parasites For Disease and Pest Control", for PI Liwang Cui. The word "malaise" was changed to "malaria".
Committee vote: 9 ayes, 0 nays, 0 abstentions.

New Business/ Compliance Coordinators Report:

- Utilizing materials that are Exempt according to NIH guidelines – Discussion - AALAS Article, "The National Institutes of Health System for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research"

The IBC discussed what process would be used to make the final determination as to whether a research project was exempt from review under the provisions outlined in the NIH guidelines. The IBC coordinator benchmarked with at least three other "Big Ten" institutions and found in each case they ask the PI's to answer a series of questions, which helped to determine if the research was exempt from committee review. The PI would make a recommendation of exemption to the IBC, which was then confirmed and finalized by each entity's IBC.

It was discussed that the information acquired through benchmarking was outlined in a report to Penn State's Institutional Official and University attorneys. The IO and attorneys strongly suggested the final determination should be made by Penn State's IBC. The IBC coordinator asked that the committee members consider the information provided and the suggestions from the IO and PSU attorneys while assisting in the development of the process PSU will follow. A majority of the committee agreed, during discussion, that some entity other than the PI should be involved in the exemption determination process. They also agreed a series of questions should be asked of the PI's to serve as an exemption prescreening. The final thought before tabling the issue for finalization at the next meeting was that the PI could be involved by making the preliminary determination but for accounting purposed the determination will be confirmed by the IBC. To

To help the committee members develop the questions to be used during the prescreening, they were supplied with a packets of information the second week of June and were asked to reply with email comments by the end of the June. The packet included portions of the NIH guidelines, sample applications used by other institutions and a copy of the memo sent to the IO and PSU attorneys. Everyone in attendance agreed to review the information and provide their recommendations. It was agreed the issue would be finalized during the next meeting of the rDNA Biosafety committee.

- **Use of retro-virus as a vector system** - The committee briefly discussed whether there were any safety concerns associated with using retro-virus packaging systems as vectors when conducting transgenic work. Most agreed the risk to staff shouldn't be any greater than those risks posed by the current systems being used, but it was agreed that the committee members would take a closer look and determine if additional concerns need to be considered. The IBC tabled discussion of this topic until the next IBC meeting.

Biosafety Officer's Report:

C. Speaker was not present at this meeting.

The meeting adjourned at 11:00 am.

The next meeting is scheduled for July 7, 2004 in 212 Kern Graduate Building.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES – rDNA Meeting
201 Kern Graduate Building
August 14, 2004**

Members Present: Aziz Ben-Jebria, Maurine Claver, Jeffery Dodds, William Greer, Andrew Henderson, Teh-Hui Kao, Laura Klein, Jeffrey Peters, Elaine Schuckers, Curtis Speaker, Gretchen Kuldau

Members Absent: Herbert Cole, Pamela Correll, Douglas Granger, Charles Howsare, Carlton Miller, Daniel Shaw, Candice Yekel

Others Attending: Erica Kresovich, Jacqueline Gardner

The meeting was called to order at 10:47 am. IBC Chair, Daniel Shaw and IBC Vice-Chair, Herbert Cole were both unavailable for this meeting. Therefore, W. Greer presided as chair.

This is the first rDNA IBC meeting separate from the regular monthly IBC meeting, therefore, there are no previous meeting minutes.

Subcommittee Activity Reports (May 18, 2004 – July 22, 2004)(Attachment A):

The IBC reviewed the attached rDNA and rDNA-Exempt subcommittee activity reports.

After review, the IBC noted that there is no summary for the following IBC protocols and that they request E. Kresovich to check these files:

- Richard Cyr # 19096
- David Braun # 19118

The subcommittee activity reports were approved with this noted. Committee vote: 11 ayes; 0 nays; 0 abstentions.

New Business/ Compliance Coordinators Report:

- Discussion – Determining rDNA exemptions

Prior to this meeting, W. Greer sent information to the IBC regarding the review of rDNA research. The issue continues to be whether or not the IBC should be responsible for determining if rDNA research is exempt from review according to NIH guidelines. After discussion, the IBC decided the following; (1) all investigators working with rDNA at Penn State must submit an application to the Office for Research Protections for prescreening, IBC review and approval; (2) point 5 in the definition section of Penn State Policy SY-24 will be edited to say "Recombinant DNA" and (3) revise the question 8 on the IBC research application. The rDNA subcommittee members have agreed to review question 8 and offer suggestions and revisions. The members will e-mail W. Greer their comments and/or suggestions, which will be collected and discussed during a subcommittee meeting. The subcommittee will revise question 8 and the proposed changes will be brought to the rDNA Biosafety Committee for final approval.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES – rDNA Meeting
201 Kern Graduate Building
August 14, 2004**

➤ **NIH's guidelines – IBC Roles and Responsibilities – UPDATED INFORMATION**

According to new NIH guidelines posted on their website, <http://www4.od.nih.gov/oba/IBC/IBCrrole.htm>, IBC's are required to meet face to face to discuss and approve rDNA research protocols requiring IBC review. After consultation with representatives for the Office of Biotechnology Affairs, it was determined that PSU should approve rDNA research protocols (requiring review) during IBC meetings. After discussion, the IBC decided that we need to determine what percent of the submitted research requires IBC review prior to investigators beginning their research.

The meeting adjourned at 11:45 am.

The September IBC meeting has been cancelled.

The next meeting is scheduled for October 6, 2004 in 212 Kern Graduate Building.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
October 6, 2004**

Members Present: Herbert Cole, Jeffery Dodds, William Greer, Andrew Henderson, Charles Howsare, Gretchen Kuldau, Carlton Miller, Daniel Shaw, Curtis Speaker, Candice Yekel

Members Absent: Maurine Claver, Douglas Granger, Teh-Hui Kao, Laura Klein, Jeffrey Peters, Elaine Schuckers

Others Attending: Jacqueline Gardner, Erica Kresovich, Douglas Kuhn – Manager of Biological and Environmental Health, PSU - Hershey

The meeting was called to order at 10:41 am by IBC Chair Daniel Shaw.

Previous Meeting Minutes (August 12, 2004):

No changes were noted to the August 12, 2004 meeting minutes; therefore Jeffery Dodds motioned for approval. Andrew Henderson seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (July 22, 2004 – September 21, 2004):

The IBC reviewed the attached rDNA and rDNA-Exempt subcommittee activity reports. After discussion, the following was recommended:

1. It was suggested that Curt Speaker confirm that BL-1 is the appropriate Biosafety Level for the necessary containment for IBC# 19212; PI Diana Cox-Foster.
2. William Greer agreed to confirm with Gary Felton, IBC# 19275, that he is in fact not using animals in his research.
3. IBC members stated that a few reviewers are not providing enough information/comments when reviewing IBC protocols. It was agreed that additional comments would be made if the reviews comments did not thoroughly discuss the project.

New Business/ Compliance Coordinators Report:

Documents for Reviewing and Approving rDNA protocols -

On September 29, 2004, the rDNA subcommittee (Andrew Henderson, Teh-Hui Kao, Gretchen Kuldau, and William Greer) met to discuss and revise the rDNA questions on the Application for the Use of Biohazardous Materials. William Greer compiled their decisions and revised the questions regarding rDNA, which will be asked on the IBC submission application. After review of the questions, the IBC decided the following:

1. Item B on the document titled, "rDNA Questions on IBC Application – Revisions", it was suggested that William Greer contact the Office for Biotechnology Activities (OBA) to inquire whether the NIH rDNA guideline referring to 10 Liters is for a cumulative amount or referring to an amount obtained through one experiment.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
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2. Combine item A and tem C on the document titled, "rDNA Questions on IBC Application – Revisions" and add the questions
 - i. "Please list the appropriate Biosafety Level for the Biohazardous Material you propose to use. If exempt, please describe why." (add a check box to the application)
 - ii. Please describe the containment of the Biohazardous materials that you propose to use.

An SOP was also prepared to serve as a resource for ORP when prescreening rDNA protocols.

1. Number 4, in the SOP will be split into two separate questions. Letters a-h require committee review, and will remain under question #4. Letters i-s are the criteria that describe exempt rDNA research categories and will be listed under a new number which will be question # 5.
2. The SOP will be used during ORP's prescreening of rDNA research applications. If a positive determination on the review type cannot be made using the SOP, ORP will defer this decision to one of the rDNA reviewers.
3. If the research is determined to be exempt (using the SOP for guidance), the Principal Investigator will be notified that he/she may begin the research. The Office for Research Protections will grant final approval for the research application. Approval must be maintained for the life of the project to ensure compliance.
4. The following sentence was added to the Applicability on the SOP "This SOP does not supercede the NIH guidelines, but is a tool to aid in reviewing rDNA research protocols".

Assurance Page of the IBC application will also be modified;

1. On the Assurances (signature) page of the Application, under #6, add "and University Policy SY-29" to the end of the sentence.
2. On the Assurance (signature) page of the Application, remove the lines created for the PI to initial and replace them with Yes/No checkboxes (the checkboxes will be put on the page when the application wizards are implemented).

William Greer informed the IBC that they are to send any additional comments regarding the SOP to him for consideration. After discussion of the above items the IBC approved these changes.
Committee vote: 10 ayes; 0 nays; 0 abstentions.

FYI –

William Greer and Curtis Speaker will be presenting a Brown Bag luncheon titled, "Unraveling the Legalities of rDNA Research: Who is Liable for Compliance – the Institution or the Researcher?" on October 29, 2004 in room 102 Kern Graduate Building.

Charles Howsare will be attending a Risk Assessment Conference at Harvard University the week of October 11th, 2004 and will report any new information to the IBC at the next meeting.

Herbert Cole motioned for adjournment. Jeffery Dodds seconded the motion. The meeting adjourned at 11:33 a.m.

The September IBC meeting has been cancelled.

The next meeting is scheduled for November 3, 2004 in 212 Kern Graduate Building.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
December 1, 2004**

Members Present: Maurine Claver, Herbert Cole, Jeffery Dodds, William Greer, Teh-Hui Kao, Elaine Schuckers, Curt Speaker

Members Absent: Douglas Granger, Andrew Henderson, Charles Howsare, Laura Klein, Gretchen Kuldau, Carlton Miller, Daniel Shaw, Candice Yekel

Others Attending: Jackie Gardner, Erica Kresovich, Matthew Toniatti (on behalf of Charles Howsare, from the Occupational Medicine Office)

Dr. Daniel Shaw was absent from this meeting, therefore, Dr. Herbert Cole presided as Chair. The meeting was called to order at 10:03 am.

IBC Compliance Coordinator introduced and welcomed Matthew Toniatti to the IBC meeting. Matt is attending this meeting on behalf of Charles Howsare and the Occupational Medicine Office for the discussion involving the health concerns working with Tamarins.

Previous Meeting Minutes (October 6, 2004):

No changes were noted to the October 6, 2004 meeting minutes; therefore they were unanimously approved. Committee vote: 7 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (July 22, 2004 – September 21, 2004):

The IBC reviewed and approved, with no changes, the attached rDNA and rDNA-Exempt subcommittee activity reports. Committee vote: 7 ayes; 0 nays; 0 abstentions.

New Business:

FYI – The Biological Safety Officer informed the IBC that he will not be re-inspecting the laboratories of the Principal Investigators who have moved into the new Life Sciences and/or Chemistry buildings. He will wait until their current inspection expires and then at that time, he will inspect the new laboratory location(s).

Review and Approval of SOP for reviewing rDNA research protocols:

This standard operating procedure was created in order to ensure that the IBC is fulfilling the NIH requirements outlined in the Guidelines for Research Involving Recombinant DNA for the proper review of protocols utilizing rDNA. This SOP will aid the IBC Compliance Coordinator and the IBC on the procedures to be followed when reviewing Biosafety protocols that involve rDNA. The coordinator clarified with the Office of Biotechnology Affairs that the 10L reference in the guidelines is referring to a large scale production rather than an accumulative amount. It was suggested that a reference to SY-24 be added to the Applicability section of this SOP. After discussion, the IBC voted to approve this document. The committee also agreed to add "In the event the IBC Coordinator is on extended leave, a rDNA committee member will perform the rDNA reviews typically handled by the coordinator." Teh-Hui Kao motioned for approval of this SOP. Elaine Schuckers seconded the motion. Committee vote: 7 ayes; 0 abstentions; 0 nays

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
December 1, 2004**

Review and Approval of:

a. Policy IBC2A – Oversight of Transgenic Mice Biohazards

A few suggestions for change were made regarding this policy. On the first page under the heading Applicability, the second sentence should be changed to read “This policy applies to all University locations, except for the College of Medicine at Hershey which maintains their own assurances.

Under the definition for Transgenic Mice, it was suggested that we compare this paragraph to the rDNA guidelines for generating transgenic animals to ensure consistency. Jeffery Dodds motioned for approval of this policy. Maurine Claver seconded the motion. Committee vote: 7 ayes; 0 nays; 0 abstentions.

Biosafety Officer’s Report:

Curt Speaker provided an update regarding research involving mites and honeybees. The control and the experimental population are going to be separated by distance. The experimental group is going to be housed by the University Park airport and the virus-free group is going to be housed at Rock Springs. Also, the state bee inspector is the Co-PI on this project.

The meeting adjourned at 10:21 a.m.

The next meeting is scheduled for January 5, 2005 in 212 Kern Graduate Building.

These minutes were prepared by Erica M. Kresovich and reviewed by William G. Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
February 2, 2005**

Members Present: H. Cole, Jeffery Dodds, William Greer, Gretchen Kuldau, Teh-Hui Kao, Carlton Miller, Jeffrey Peters, Daniel Shaw, Curtis Speaker, Candice Yekel

Members Absent: Maurine Claver, Pamela Correll, Douglas Granger, Andrew Henderson, Charles Howsare, Laura Klein, Michael Pishko, Elaine Schuckers

Others Attending: Jackie Gardner and Erica Kresovich

The meeting was called to order at 11:04 am, Daniel Shaw presided as Chair.

Previous Meeting's Minutes (December 1, 2004) (Attachment A):

No changes were noted to the meeting minutes; therefore, C. Speaker motioned for approval. W. Greer seconded the motion. Committee vote: 9 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (November 16, 2004 – January 18, 2005) Attachment B):

One change was noted on the rDNA approval report. Page 2 of 8, under the comments section of Craig Cameron's IBC# 19901, the sentence "Although the project may be exempt....." was changed to read "Although the project may be exempt.....". The report was approved contingent upon this change. Committee vote: 9 ayes; 0 nays; 0 abstentions.

NEW BUSINESS: Full Reviews

Craig Cameron, IBC# 20076, "Regulation of Poliovirus Transcription and Regulation" –

After discussion of Dr. Cameron's Biosafety protocol, it was found to be NON-exempt from NIH's rDNA guidelines and the IBC voted to grant approval to the proposed research.

Nina Fedoroff, IBC# 20200, "Controlled Deletional Mutagenesis and Gene Homing in Arabidopsis" –

After discussion of Dr. Fedoroff's Biosafety protocol, it was found to be exempt from NIH's guidelines, but agreed full approval should be granted to the project.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
February 2, 2005**

Clarification regarding IBC Policies and the term “transgenic mice” –

This is a follow up to a previous discussion from the December 1, 2004 IBC meeting regarding the clarification of the terms “transgenic mice”. The Institutional Biosafety Committee *Policy IBC2A – Oversight of Transgenic Mice* states that transgenic mice are animals with a genome that has been altered by the stable introduction of recombinant DNA into the animal’s germ-line (transgenic animals) and that are NOT expressing hazardous materials or shedding viable organisms (viral vectors). J. Dodds raised questions regarding this policy. He agreed to send W. Greer information with specific questions that he would like answered regarding the generating of transgenic mice. After review and through email correspondence with those expressing concerns about the policy. It was agreed the policy should stand as written.

Compliance Coordinator’s Report:

The Office of Biotechnology Affairs (OBA) has announced that they will begin conducting site-visits of all institutions that utilize rDNA in research activities. W. Greer stated that he is preparing for OBA to come to Penn State. He provided a copy of an announcement from OBA to the IBC as well as an announcement from the Office for Research Protections to all Principal Investigators’ that use rDNA in their research.

The meeting adjourned at 11:23 am.

The next meeting is scheduled for March 2, 2005 in 212 Kern Graduate Building.

These minutes were prepared by Erica Kresovich and reviewed by William Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
March 2, 2005**

Members Present: M. Claver, H. Cole, J. Dodds, W. Greer, C. Howsare, T. Kao, G. Kulda, C. Miller, M. Pishko, C. Speaker

Members Absent: P. Correll, D. Granger, A. Henderson, L. Klein, J. Peters, E. Schuckers, D. Shaw, C. Yekel

Others Attending: Erica Kresovich

The meeting was called to order at 10:15 am. H. Cole presided as Chair in D. Shaw's absence.

Previous Meeting's Minutes (February 2, 2005) (Attachment A):

No changes were noted to the meeting minutes; therefore, they were unanimously approved. Committee vote: 10 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (January 18, 2005 to February 16, 2005) Attachment B):

No changes were noted to the approval reports; therefore, they were unanimously approved. Committee vote: 10 ayes; 0 nays; 0 abstentions.

NEW BUSINESS:

Full review of rDNA research protocols:

IBC# 20363 – After discussion, the IBC voted to approve the laboratory work only. Approval of the field work will not be granted until a copy of the APHIS permit is received and is reviewed and approved by the IBC. A site inspection of Rock Springs is also necessary to ensure proper isolation. C. Howsare motioned for approval. **This research is not-exempt from the NIH's rDNA guidelines.** G. Kulda seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

IBC# 19949 – The IBC unanimously approved this protocol. **This research is exempt from the NIH's rDNA guidelines.** G. Kulda motioned for approval. C. Speaker seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

IBC# 20430 – After discussion, the IBC agreed that the BL-3 level on the reviewer sheet is correct. **This research is not exempt from the NIH's rDNA guidelines.** C. Howsare motioned for approval. T. Kao seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

IBC# 20482 – The IBC approved this protocol with no comments. M. Claver motioned for approval; W. Greer seconded the motion. **This research is not exempt from the NIH's rDNA guidelines.** Committee vote: 10 ayes; 0 nays; 0 abstentions.

IBC# 19741 – After discussion, the IBC determined that **this research is exempt from NIH's rDNA guidelines;** therefore, G. Kulda motioned for approval. C. Speaker seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions.

IBC# 20246 – The IBC had no comments regarding this protocol. C. Speaker motioned for approval. C. Howsare seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions. **This research is not exempt from the NIH's rDNA guidelines.**

IBC# 20244 – The use cell lines in this protocol have been addressed in the IACUC protocol (testing for murine pathogens). After discussion, the IBC voted to approve this protocol contingent on the following statement: **"Final approval will not be granted until all personnel have completed the blood borne pathogen training."** G. Kulda motioned for approval. C. Howsare seconded the motion. Committee vote: 10 ayes; 0 nays; 0 abstentions. **This research is not exempt from the NIH's rDNA guidelines.**

Compliance Coordinator's Report:

FYI - OBA (Office of Biotechnology Affairs – Department of NIH) is sponsoring rDNA workshops for interpreting and implementing the NIH's Guidelines for reviewing rDNA research. W. Greer asked OBA to consider holding one of these workshops at PSU. To date, no response has been received by OBA.

The meeting adjourned at 10:54 am.

The next meeting is scheduled for April 6, 2005 in 212 Kern Graduate Building.

These minutes were prepared by Erica Kresovich and reviewed by William Greer.

OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
April 6, 2005

Members Present: M. Claver, H. Cole, J. Dodds, W. Greer, T. Kao, C. Miller, M. Pishko, C. Speaker, E. Schuckers, D. Shaw

Members Absent: P. Correll, D. Granger, A. Henderson, C. Howsare, L. Klein, G. Kuldau, J. Peters, C. Yekel

Others Attending: J. Gardner and E. Kresovich

The meeting was called to order at 10:28 am by the IBC Chair, Dr. Daniel Shaw.

Previous Meeting's Minutes (March 2, 2005) (Attachment A):

No changes were noted to the March 2, 2005 rDNA meeting minutes; therefore J. Dodds motioned for approval. C. Speaker seconded the motion. Committee vote: 11 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (February 16, 2005 to March 18, 2005) Attachment B):

No changes were noted to these reports; therefore, they were unanimously approved. Committee vote: 11 ayes; 0 nays; 0 abstentions.

NEW BUSINESS:

Security of Rock Springs – One of the IBC Community Members asked about the security of Rock Springs in regards to the research that is conducted there. W. Greer informed her that there is an animal facility with someone who lives on site and that the animal facilities are always locked. As far as Biosafety research activities are concerned, there is really no security per se. M. Claver stated that University police have jurisdiction of that area as well and that there is 2 levels of security. One is the overall property and on-site management the other is that the security is based on the research. Other than it being a remote location, there is no real security of this area.

IBC# 19156 - After discussion, C. Speaker motioned for approval. E. Schuckers seconded the motion. **This project is not exempt from NIH's rDNA guidelines.**

IBC# 15747 - After discussion, J. Dodds motioned for approval. W. Greer seconded the motion. **This project is not exempt from NIH's rDNA guidelines**

IBC# 20555 - After discussion, D. Shaw motioned for approval. J. Dodds seconded the motion. **This project is not exempt from NIH's rDNA guidelines.**

IBC# 20485 - After discussion, J. Dodds motioned for approval and H. Cole seconded the motion with the following statement added to the approval letter, **"If you ever anticipate receiving a mosquito colony, this must first be approved by the Institutional Biosafety Committee"**. **This project is not exempt from NIH's rDNA guidelines.**

OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
April 6, 2005

Compliance Coordinator's Report:

W. Greer provided the IBC with an update of the number of currently reviewed and approved Biosafety protocols (see below):

		Percent of Total	
Total IBC Protocols:	311	N/A	
Total Pathogen Protocols:	165	53%	none here > 50% with
Total Carcinogen/Toxin Protocols:	15	5%	
Total rDNA Protocols:	98	32%	
Total rDNA and Pathogen Protocols:	22	7%	
Total rDNA and Carcinogen/Toxin Protocols:	11	4%	
		100%	
Total Protocols Associated with IACUC protocols:	55		
Total Protocols involving rDNA:	131		
	rDNA exempt:	27	
	rDNA non-exempt:	11	
	rDNA registered:	17	
Total rDNA protocols reviewed for EXEMPTION status:	55	42%	

Biosafety Officer's Report-

- none -

The meeting adjourned at 11:03 am.

The next meeting is scheduled for May 4, 2005 in 212 Kern Graduate Building.

These minutes were prepared by Erica Kresovich and reviewed by William Greer.

OFFICE FOR RESEARCH PROTECTIONS (ORP)

rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES

201 Kern Graduate Building

May 4, 2005

Members Present: H. Cole, J. Dodds, W. Greer, T. Kao, G. Kuldau, C. Miller, J. Peters, E. Schuckers, D. Shaw, C. Speaker

Members Absent: P. Correll, D. Granger, A. Henderson, C. Howsare, L. Klein, M. Pishko, C. Yekel

Others Attending: J. Gardner and E. Kresovich

The meeting was called to order at 10:33 am by the IBC Chair, Dr. Daniel Shaw.

Previous Meeting's Minutes (April 6, 2005) (Attachment A):

It was noted that G. Kuldau was not present at the April 6th meeting. The minutes were approved as corrected. Committee vote: 9 ayes; 0 nays; 0 abstentions.

Subcommittee Activity Reports (March 19, 2005 – April 25, 2005) Attachment B):

The following changes were made to the approval reports; (1) the IBC asked that the ORP staff be consistent with the way the words "exempt and non exempt" are capitalized in the reports; (2) on page 2 of 10, IBC# 19156, the BL-3 indication in the summary should be changed to BL-2; (3) on page 4 of 10, # 20740 is listed as being a BL-1, but it should be changed to BL-2; (4) on page 5 of 10, # 15474, should be BL-3. There was some discrepancy between as to what exactly the Biosafety Level should be required for this protocol. C. Speaker offered to follow up with the Principal Investigator regarding this issue; (5) on page 8 of 10, #20555, the last statement of the summary should read, "not exempt" and "The summary was reviewed by the IBC for approval" should also be added; (6) on page 9 of 10, the following statement needs to be added to the summary. "This summary was reviewed by the IBC."

J. Dodds motioned to approve the reports, therefore; G. Kuldau seconded the motion. Committee vote: 9 ayes; 0 abstentions; 0 nays.

NEW BUSINESS:

The following protocols were discussed, reviewed and approved by the full Biosafety committee:

IBC# 18818 – Committee vote: 11 ayes; 0 nays; 0 abstentions.

IBC# 18784 – Committee vote: 11 ayes; 0 nays; 0 abstentions.

IBC# 19986 – Committee vote: 11 ayes; 0 nays; 0 abstentions.

IBC# 16115 – Committee vote: 11 ayes; 0 nays; 0 abstentions.

IBC# 20980 – Committee vote: 11 ayes; 0 nays; 0 abstentions.

IBC# 20912 – Committee vote: 11 ayes; 0 nays; 0 abstentions.

Compliance Coordinator's Report:

- none-

Biosafety Officer's Report-

- none -

The meeting adjourned at 10:57 am.

The next meeting is scheduled for June 1, 2005 in 212 Kern Graduate Building.

These minutes were prepared by Erica Kresovich and reviewed by William Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
June 1, 2005**

Members Present: H. Cole, P. Correll, B. He, A. Henderson, T. Kao, G. Kuldau, C. Miller, M. Pishko, J. Peters, D. Shaw, C. Speaker

Members Absent: J. Dodds, D. Granger, C. Howsare, L. Klein

Others Attending: J. Gardner, E. Kresovich

The meeting was called to order at 10:33 am by the IBC Chair, Dr. Daniel Shaw.

Previous Meeting's Minutes (May 4, 2005) (Attachment A):

No changes were noted to the minutes therefore, they were unanimously approved. Committee vote: 11 ayes; 0 ayes; 0 abstentions.

Subcommittee Activity Reports (April 25, 2005 – May 24, 2005) Attachment B):

A few changes were noted to these reports, (1) on page 7 of 8 under IBC# 15861, the second to last sentence in the paragraph was change to read "the protein will be expressed but is not toxic", (2) on page 5 of 8, the word Escheridia was changed to Eschericia. The approval reports were approved contingent upon these changes. Committee vote: 11 ayes; 0 nays; 0 abstentions.

New Business:

There were no rDNA protocols to be discussed and/or approved at this meeting.

Compliance Coordinator's Report:

- none -

Biosafety Officer's Report-

-none-

The meeting adjourned at 10:35 am.

The next meeting is scheduled for July 6, 2005 in 212 Kern Graduate Building.

These minutes were prepared by Erica Kresovich and reviewed by William Greer.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
July 5, 2005**

Members Present: M. Claver, J. Dodds, B. He, W. Greer, T. Kao, G. Kuldau, C. Miller, D. Shaw, E. Schuckers, C. Speaker

Members Absent: H. Cole, P. Correll, D. Granger, A. Henderson, C. Howsare, L. Klein, J. Peters, M. Pishko, C. Yekel

Others Attending: J. Gardner, E. Kresovich

The meeting was called to order at 11:05 am by the IBC Chair, Dr. Daniel Shaw.

PREVIOUS MEETING'S MINUTES (July 5, 2005) (Attachment A):

It was noted that the time that the June 1st IBC meeting was called to order needs to be revised. The minutes were approved contingent upon this change. Committee vote: 10 ayes; 0 nays; 0 abstentions.

SUBCOMMITTEE ACTIVITY REPORTS (May 25, 2005 – June 22, 2005) Attachment B):

No changes were noted the reports; therefore, they were unanimously approved. Committee vote: 10 ayes; 0 nays; 0 abstentions.

NEW BUSINESS:

IBC# 19008 – The IBC reviewed and approved this research protocol with no comments. Committee vote: 10 ayes; 0 nays; 0 abstentions.

COMPLIANCE COORDINATOR'S REPORT:

As an FYI, a copy of the article from the June 2006 Human Research Report titled, "IBC's Should be Regulated like IRB's", written by Ed Hammond of the Sunshine Project, was provided to the IBC prior to the meeting.

BIOSAFETY OFFICER'S REPORT-

-none-

IBC Chair, D. Shaw, announced that he is leaving PSU and therefore resigning from his position on the committee. The IBC thanked D. Shaw for his efforts and job well done.

The meeting adjourned at 11:1 am.

The next meeting is scheduled for August 3, 2005 in 102 Kern Graduate Building.

These minutes were prepared by E. Kresovich, IBC Assistant, and were reviewed by W. Greer, IBC Coordinator.

OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
201 Kern Graduate Building
August 3, 2005

Members Present: M. Claver, J. Dodds, B. He, W. Greer, E. Schuckers, C. Speaker

Members Absent: P. Correll, D. Granger, A. Henderson, C. Howsare, T. Kao, L. Klein, G. Kulda, C. Miller, J. Peters, M. Pishko, C. Yekel

Others Attending: E. Kresovich

The meeting was called to order at 10:30 am by the IBC Coordinator, W. Greer. Office for Research Protections, Candice Yekel, will serve as chair until a new IBC chair is selected.

PREVIOUS MEETING'S MINUTES (August 3, 2005) (Attachment A):

No changes were noted to the minutes; therefore E. Schuckers motioned for approval. J. Dodds seconded the motion. Committee vote: 6 ayes; 0 nays; 0 abstentions.

rDNA SUBCOMMITTEE ACTIVITY REPORTS (June 22, 2005 – July 19, 2005) Attachment B):

The following comments/ changes were noted to the reports: (1) IBC# 19008; BL-1 indicated however reviewer's comments indicate BL-2 for Greenhouses where the work will be conducted. C. Speaker indicated that he will verify the Biosafety Level of the Greenhouses.

FULL REVIEW:

IBC# 19533 – This protocol was reviewed and approved by the full IBC. E. Schuckers commented that the IBC should ensure that Dr. Pell is aware of the nature of this research that it is occurring at Penn State University. M. Claver stated that she and C. Yekel will speak with Dr. Pell regarding this research.

IBC# 21214 – This protocol was reviewed and approved contingent on the Office for Research Protections receipt of the following comments: (1) question #8a was not answered, (2) PI indicates on the application that he is using Select Agents, however he is not, please correct this in the application, (3) PI needs to explain further what he proposes to do with rDNA, (4) resolve concerns regarding Animal/Biohazard Safety Form. W. Greer will contact the PI for this additional information.

The PI is using the same biohazard that another PSU researcher also uses. The IBC noticed a discrepancy between this PI's information and the other PI's information on the Animal/Biohazard Safety Forms regarding the length of time that the PI states the animal caretakers should wait before cleaning and changing the bedding in his animal cages. J. Dodds suggested that the PI's should clean their cages at least 1 time after each application of the biohazard before the animal caretakers are responsible for cleaning it. C. Speaker will speak with these PI's to resolve this discrepancy and PSU's Animal Facilities Coordinator, D. Carey, regarding this issue and offer the IBC's suggested changes. After discussion, the IBC approved the protocol, **EXCEPT** for the proposed procedures that involve rDNA. Once the PI clarifies this information, he will be asked to submit a modification that will require separate approval by the IBC. Committee vote: 6 ayes; 0 nays; 0 abstentions.

OFFICE FOR RESEARCH PROTECTIONS (ORP)

rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES

DRAFT

201 Kern Graduate Building

August 3, 2005

NEW BUSINESS:

Animal/Biohazard Safety Forms

E. Schuckers posed a few questions regarding the Animal/Biohazard Safety Form. She asked who was to be contacted and what should the procedure be if the personnel listed on the form are not able to be located. C. Speaker informed her that the personnel from the Animal Resource Program are would be responsible for the animals in an event that the contacts cannot be located. J. Dodds stated that this PI has a very similar protocol to this with the exact treatment, but that some of the safety procedures are different. He also stated that he has a few concerns regarding these forms. The Animal Resource Program is concerned about their caretakers handling biohazards that may exist. He stated that there are 2 PI's that are working with the same Biohazardous materials, however, they have different information regarding their safety procedures. Also, the PI's are supposed to be writing these forms with the help of the animal facilities coordinator and the biosafety officer. However, the PI is writing these forms on their own, which then may warrant future revisions and/or changes. C. Speaker stated that he prefers to continue to handle these forms as they are now; to give the PI a chance to write the form, and if things are incorrect, to work with the PI at that point. After discussion, the IBC agreed that C. Speaker and J. Dodds monitor this situation and the IBC will revisit this issue in six months, or before if problems arise.

COMPLIANCE COORDINATOR'S REPORT:

- none -

BIOSAFETY OFFICER'S REPORT-

-none-

The meeting adjourned at 11:28 am.

The next meeting is scheduled for September 7, 2005 in 102 Kern Graduate Building.

These minutes were prepared by E. Kresovich, IBC Assistant, and were reviewed by W. Greer, IBC Coordinator.

OFFICE FOR RESEARCH PROTECTIONS (ORP)

DRAFT

rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES

201 Kern Graduate Building

September 7, 2005

Members Present: M. Claver, J. Dodds, B. He, W. Greer, C. Miller, E. Schuckers, C. Speaker

Members Absent: P. Correll, D. Granger, A. Henderson, C. Howsare, T. Kao, L. Klein, G. Kuldau, J. Peters, M. Pishko, C. Yekel

Others Attending: E. Kresovich, M. Spear

The meeting was called to order at 11:31 am by the IBC Coordinator, W. Greer. The Office for Research Protections Director, Candice Yekel, will serve as chair until a new IBC chair is selected.

PREVIOUS MEETING'S MINUTES (August 3, 2005) (Attachment A):

No changes were noted to the minutes; therefore J. Dodds motioned for approval. C. Speaker seconded the motion. Committee vote: 7 ayes; 0 nays; 0 absentions.

rDNA SUBCOMMITTEE ACTIVITY REPORTS (July 20, 2005 – August 15, 2005) Attachment B):

The following questions/concerns were stated: 1) on page 1 of 1, #19275 – what viruses are being used?; 2) on page 3 of 7, # 21214, the words “transgenic mice” in the second to last sentence in the comments needs to be changed to “toxin”; 3) on page 7 of 7, did the Office for Research Protections (ORP) receive an APHIS permit and how is the corn being contained? W. Greer stated that the ORP did receive a permit from the PI. C. Speaker informed the IBC that the PI is to adhere to the containment guidelines set by APHIS in the permit and that it is the PI responsibility to follow those as such.

FULL REVIEW:

-none-

NEW BUSINESS:

- none-

COMPLIANCE COORDINATOR'S REPORT:

- none -

BIOSAFETY OFFICER'S REPORT-

-none-

The meeting adjourned at 11:36 am.

The next meeting is scheduled for October 5, 2005 in 102 Kern Graduate Building.

These minutes were prepared by E. Kresovich, IBC Assistant, and were reviewed by W. Greer, IBC Coordinator.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
102 Kern Graduate Building
October 5, 2005**

Members Present: M. Claver, J. Dodds, W. Greer, B. He, C. Miller, M. Pishko, E. Schuckers, C. Speaker, C. Yekel

Members Absent: P. Correll, D. Granger, A. Henderson, C. Howsare, T. Kao, L. Klein, G. Kulda, J. Peters

Others Attending: A. Brumbaugh, E. Kresovich

The meeting was called to order at 10:47a.m. by IBC Acting Committee Chair, C. Yekel. C. Yekel, Director, The Office for Research Protections, will serve as Chair until a new IBC chair is selected.

PREVIOUS MEETING'S MINUTES (September 7, 2005) (Attachment A):

No changes were noted to the minutes; therefore a motion for approval was made and seconded. Committee vote: 9 ayes; 0 nays; 0 abstentions.

rDNA SUBCOMMITTEE ACTIVITY REPORTS (August 16, 2005 – September 28, 2005) (Attachment B):

Reviewed by committee – no comments.

NEW BUSINESS:

FULL REVIEW

IBC #19545 (Attachment C)

Compliance Coordinator reported that the protocol is an annual review and that, upon review, the Compliance Coordinator noted that the volume of 20 Liters requires a full committee review and approval (as with any volumes over 10 Liters). The Compliance Coordinator reported that the research proposed is not particularly hazardous; it's just a matter of collecting enough paste of E. Coli bacteria to produce the desired DNA. Compliance Coordinator reported that the PI intends to grow in a fermenter and be able to, in one shot, collect enough grams of recombinant E. Coli paste to extract the desired DNA.

A motion to approve the protocol was made and seconded. Committee vote: 9 ayes; 0 nays; 0 abstentions.

COMPLIANCE COORDINATOR'S REPORT:

- none -

BIOSAFETY OFFICER'S REPORT-

-none-

The meeting adjourned at 11:50a.m.

The next meeting is scheduled for November 2, 2005 in 102 Kern Graduate Building.

These minutes were prepared by A. Brumbaugh, Staff Assistant, and were reviewed by W. Greer, IBC Coordinator.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
102 Kern Graduate Building
December 7, 2005**

Members Present: M. Claver, J. Dodds, W. Greer, G. Kuldau, C. Miller, M. Pishko, E. Schuckers, C. Speaker, C. Yekel

Members Absent: P. Correll, D. Granger, B. He, A. Henderson, T. Kao, L. Klein, J. Peters

Others Attending: A. Brumbaugh, E. Kresovich, H. Cole

The meeting was called to order at 11:37a.m. by IBC Acting Committee Chair, C. Yekel. C. Yekel, Director, The Office for Research Protections, will serve as Chair until a new IBC chair is selected.

PREVIOUS MEETING'S MINUTES (October 5, 2005):

No changes were noted to the minutes; therefore a motion for approval was made and seconded. Committee vote: 9 ayes; 0 nays; 0 abstentions.

rDNA SUBCOMMITTEE ACTIVITY REPORTS (September 29, 2005 – November 15, 2005):

Reviewed by committee – no comments.

IBC ANNUAL REVIEW OF APPLICATION AND SOP:

- The committee was asked for comment on the following current IBC Applications and SOP that were distributed to the committee on November 21, 2005:
 - Application for the Use of Biohazardous Materials (rDNA research questions)
 - SOP IBC1B – Reviewing and Approving rDNA Protocols
- A motion to approve the above IBC Application and SOP as is for another year was made and seconded. Committee vote: 9 ayes; 0 nays; 0 abstentions.

NEW BUSINESS:

-none-

COMPLIANCE COORDINATOR'S REPORT:

- none -

BIOSAFETY OFFICER'S REPORT-

-none-

The meeting adjourned at 11:40a.m.

The next meeting is scheduled for January 4, 2006 in 114 Kern Graduate Building.

These minutes were prepared by A. Brumbaugh, Staff Assistant.

**OFFICE FOR RESEARCH PROTECTIONS (ORP)
rDNA - INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MINUTES
102 Kern Graduate Building
February 1, 2006**

Members Present: M. Claver, J. Dodds, W. Greer, B. He, C. Speaker, C. Yekel

Members Absent: P. Correll, D. Granger, A. Henderson, T. Kao, G. Kuldau, C. Miller, J. Peters, M. Pishko, E. Schuckers

Others Attending: A. Brumbaugh, E. Kresovich

The meeting was called to order at 10:16a.m. by IBC Acting Committee Chair, C. Yekel. C. Yekel, Director, The Office for Research Protections, will serve as Chair until a new IBC chair is selected.

PREVIOUS MEETING MINUTES (December 7, 2005):

- A motion to approve the minutes without change was made and seconded. Committee vote: 6 ayes; 0 nays; 0 abstentions.

rDNA APPROVAL REPORTS (November 16, 2005 – January 18, 2006):

- The report was reviewed without comment.

NEW BUSINESS:

-none-

COMPLIANCE COORDINATOR'S REPORT:

- none -

BIOSAFETY OFFICER'S REPORT:

- In response to information that was sent by the ORP to the IBC regarding the NIH Office of Biotechnology Activities' reporting requirements for Recombinant DNA research-related accidents or violations of the NIH guidelines (see Attachment A), the Biosafety Officer (when performing Biosafety inspections of rDNA) will explain to the Principal Investigators that all incidents involving personnel exposure to or accidental environmental release of rDNA must be reported to ORP and EHS. The Biosafety Officer has not heard of any cases of personnel exposure to or accidental environmental release of rDNA at PSU.
- The EHS Director requested that this reporting requirement be added to the inspection form as a reminder.
- The Compliance Coordinator added that ORP has specific methods for reporting to appropriate regulatory agencies (formal letters, committee notices, etc.).

COMMITTEE ATTENDANCE:

The committee decided, for the Spring 2006 semester (some committee members have teaching schedules that conflict with the scheduled meetings), if significant review for any protocol is required, a special meeting of the IBC including more of the faculty members may be scheduled.

The meeting adjourned at 11:19a.m.

The next meeting is scheduled for March 1, 2006 in 114 Kern Graduate Building.

These minutes were prepared by A. Brumbaugh, Staff Assistant.