



Thomas  
Jefferson  
University | Jefferson  
Medical  
College

Office of Scientific Affairs  
Institutional Biosafety Committee

Founded 1824

Jefferson Medical  
College

Jefferson College of  
Graduate Studies

Jefferson College of  
Health Professions

Jefferson University  
Physicians

April 25, 2006

Mr. Edward Hammond  
The Sunshine Project  
PO Box 41987  
Austin, TX 78704

Dear Mr. Hammond,

Enclosed are copies of the minutes from Thomas Jefferson University's  
Institutional Biosafety Committee from May 2004 through January 2006.

Since The Sunshine Foundation has already requested and received minutes from  
May 2003 through May 2004, they were not included in this submission.

Sincerely,

Gerald Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee  
Professor and Senior Associate Dean

Sue Gotta, M.S.  
Vice Chair, Institutional Biosafety Committee  
Biosafety Officer

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**May 14, 2004**

**Present:** Dr. Daviau, Ms. Deyerle, Dr. Flomenberg, Mr. Goll, Drs. Grunwald, Maksymowych, Rothstein, Ms. Shaw, Ms. Souder, Dr. Srinivasan

**Excused:** Dr. Fietelson, Ms. Gotta, Ms. Greene, Drs. Hooper, Kalf, Muse, Schnell

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Dr. Grunwald called the meeting to order at 11:13 a.m.  
Quorum (10) was met; outside member present.

Dr. Hooper, while not present, sent review/vote to Chair Dr. Grunwald; it was decided by the Chair to count Dr. Hooper's vote on the protocols.

**MINUTES:**

March 12, 2004: Approved (Total = 10; Vote: For-10, Opposed-0, Abstained-0).

**NEW PROTOCOLS:**

**J. Uitto** *Gene Transfer of ABCC6 regulator genes to mouse liver. Approved (Total = 10; Vote: For-11, Opposed-0, Abstained-0) for BL-3 practices, pending the following revisions/clarifications, to be administratively reviewed by Dr. Grunwald:*

Strike the first full sentence in the answer to #13: "animals are relatively clean".

**S. Gandy** *Role of phorbol ester receptor Munc13 in the processing of Alzheimer precursor protein (APP), the principal molecule in Alzheimer's disease pathophysiology. Approved (Total = 11; Vote: For-11, Opposed-0, Abstained-0) for BL-2 practices, pending the following revisions/clarifications, to be administratively reviewed by Dr. Grunwald:*

In 13b: do not use boilerplate, list the specific equipment being used.

There was some discussion as to whether to make this BL-3, but the Committee decided that there was more danger in transporting the materials to the BL-3 lab than just using BL-3 practices in current lab.

**Other Business:**

Dr. Grunwald discussed a Dr. Pomerantz continuation protocol; no need for the Committee to review, it will just be placed in the file.

There was a discussion as to whether the IBC is required to have a quorum to hold a meeting. From a legal perspective, Ms. Deyerle pointed out that the Committee needs to look at it's own by-laws to see if they state that the Committee will not meet unless there was a quorum. It was discussed whether a member could submit a review to the Chair if they could not make a meeting. Ms. Deyerle then pointed out that if a Member gave a vote on a protocol without having heard the discussion, there is the possibility that an issue would come up in the discussion that would change the Member's opinion and thus the vote.

Dr. Rothstein proposed the possibility of putting the discussion on the Web, for members who could not make the meeting to read and then determine their vote.

The IBC by-laws/Policy Procedures Manual will be checked for more information. The NIH Guidelines merely state that there must be at least 5 Committee Members.

**Meeting Adjourned at 11:42am**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read "Grunwald", written over the typed name.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

*GBG/taw*

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**August 20, 2004**

**Present:** Drs. Calkins, Daviau, Fietelson, Flomenberg, Mr. Goll, Ms. Gotta, Ms. Greene, Drs. Grunwald, Maksymowych, Muse, Rothstein, Ms. Shaw, Dr. Srinivasan

**Excused:** Drs. Hooper, Kalf, Schnell, Smith

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Dr. Grunwald called the meeting to order at 11:04 a.m.  
Quorum (10) was met; outside member present.

Meeting interrupted by Fire Alarm at 11:05.  
Meeting resumes at 11:30

**NEW PROTOCOLS:**

**M. Rafi** *In vivo and ex vivo gene therapy for the mouse model of globoid cell leukodystrophy using different viral vectors* **Approved (Total = 14; Vote: For-14, Opposed-0, Abstained-0) for BL-2 with BL-3 practices, pending the following revisions/clarifications, to be administratively reviewed by Dr. Grunwald:**

Clarify why BL-2 with BL-3 practices is requested; only needs to be BL-3 if there is shedding/replication of virus.

Part I, #1: answer should be "yes", potential for harm exists.

Please provide maps of the vectors.

Clarify whether recombination can occur and the likelihood of this.

#8: Language needs work; clarify reference to enzyme v. vector

(For comparison, the Committee felt that compared to Dr. Schnell's answer to the same question, the answer provided here is inadequate.)

#10: Do not autoclave items that have been bleached.

Part II, #6: this answer should be "yes".

**M. Schnell** *Cellular receptor for Rabies virus (RV) and Hepatitis C (HCV).* **Approved (Total = 14; Vote: For-14, Opposed-0, Abstained-0) for BL2 and BL3, pending the following revisions/clarifications, to be administratively reviewed by Dr. Grunwald:**

Clarify whether this is a New or Amended protocol?

Part I, # 1 is not completely answered; is this a pathogen or not?

Part I, #5 needs to be answered "YES" on the first part.

Part I, #13: no IRB approval is needed for this, answer should be "N/A".

Part II, #18: is the construct an oncogene or not?

Part II, #26: please provide vector maps.

In SOP—please include that you will have goggles or face mask available

Abstract—please give more details; please use lay language.

Note for solid waste disposal: just autoclave, no bleach.

**A. Karasev**

*Plant produced single chain antibody against HIV-1. Pre-reviewed by: Dr. Grunwald. Approved (Total = 14; Vote: For-14, Opposed-0, Abstained-0) with BL2 practices, pending the following revisions/clarifications, to be administratively reviewed by Dr. Grunwald:*

IBC gives approval for the plant-based work only, not the HIV work.  
Part I of the OSA-11 must be filled out.  
IBC needs a signed original for files.  
Please describe how you are testing biological activity.

**Discussion of OSA-11 new format:**

The Committee discussed the use of the new OSA-11 for submissions, as these protocols were the first to do so. There were some concerns that now the form is too long; there was a discussion about trying to streamline the form. Several members of the Committee felt that the questions pertaining to SOPs would not be necessary if we put into place a method whereby the investigators SOPs were permanently on file, and then with each protocol they listed if anything would be different from the normal SOPs. Many felt this was a good idea due to the fact that this information is constantly repeated for each OSA-11 that gets submitted.

It was discussed that each investigator using the new form seemed to overlook answers on the form.

There was some discussion of moving to a "certification process" similar to that used for RO-14

**OTHER BUSINESS:**

Introduction of new IBC members: Dr. Bruce Smith and Dr. Donald Jungkind.

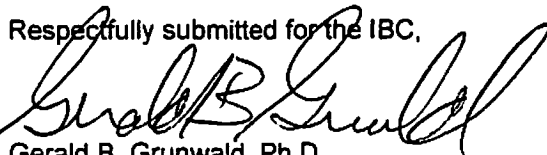
Introduction of new BSO: Sue Gotta

Comments/reactions to the electronic distribution of OSA-11 protocols for IBC meetings.

Distribution of 2003/2004 IBC Annual Report.

**Meeting Adjourned at 11:42am**

Respectfully submitted for the IBC,



Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**September 10, 2004**

**Present:** Drs. Calkins, Daviau, Fietelson, Ms. Gotta, Drs. Grunwald, Hooper, Jungkind, Kalf, Maksymowych, Rothstein, Schnell, Ms. Shaw, Dr. Smith

**Excused:** Dr. Flomenberg, Mr. Goll, Ms. Greene, Dr. Muse

**Absent:** Dr. Srinivasan

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Dr. Grunwald called the meeting to order at 11:10 a.m.  
Quorum (10) was met

Minutes: Minutes of the August 20, 2004 meeting were presented for approval; Approved: Total: 13; Vote: For-8, Opposed-0, Abstained-5 {Drs: Kalf, Hooper, Jungkind, Schnell, Smith were not present at the meeting}

**NEW PROTOCOLS:**

There were no new protocols to review at this meeting.

**OTHER BUSINESS:**

Dr. Grunwald distributed materials for the Committee to discuss:

NIH Guidelines page with information and links to the full NIH Guidelines for Recombinant DNA and Gene Transfer

Office of Biotechnologies FAQ pages about the roles and responsibilities of IBCs

Dr. Grunwald briefly went through these documents, highlighting information of particular interest, such as whether an IBC can "meet" via email. Dr. Kalf reminded the Committee that while the NIH Guidelines were primarily set up for DNA work, an Institution has the authority to use these guidelines for Pathogens work as well.

Dr. Grunwald discussed recent changes in how the administrative business of the IBC is conducted, i.e. the distribution of materials to the Committee, the distribution of approval letters to the investigators and communications between himself, the BSO and the administrative secretary. The new BSO and the administrative secretary are working to consolidate all files, with the goal in mind that the IBC needs to get a handle on ALL research being done at TJU. One mechanism to accomplish this would be an annual biosafety survey or certification for all research faculty. Our system implicitly implies that if we as a Committee only see 12 protocols a year, then everyone else is working on things that have already been approved. It is important to get information out to the research Community that if they have an IBC approval number and no significant changes, they need only do a letter of amendment.

There was some discussion concerning using the TJU IT department to help us construct a mechanism to gather the information the IBC would need and build a database. A discussion arose about the problem of TJU investigators not knowing their approval codes when asked to supply said code on grant applications. It was suggested the list of approval codes be put up on the website. The Committee was in agreement that this is something we should pursue.

The Committee discussed the order of importance in which we should be updating this information: BL-3; BL-2/3; BL-2, and BL-1.

[REDACTED]

There was a brief discussion about the new OSA-11 form. Dr. Grunwald has found a wide variety and range of types for forms which other institutions are using. At this time, there will be no further revisions or modifications to the 2004 version of the OSA 11.

There will be an announcement put forth to the research Community stating that the new form is available on line and that the IBC would no longer be accepting the old version of the form.

Dr. Kalf distributed, for the Committee's reference, an article entitled "Introduction for 'Safety Considerations for Retroviral Vectors: A Short Review'", which appeared in *Applied Biosafety*.

**Meeting Adjourned at 12:02am**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read "Gerald B. Grunwald". The signature is fluid and cursive, with the first and last names being more prominent.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**October 8, 2004**

**Present:** Drs. Daviau, Flomenberg, Mr. Goll, Ms. Gotta, Drs. Grunwald, Jungkind, Kalf, Mr. Koser, Drs., Maksymowych, Schnell, Ms. Shaw, Dr. Smith

**Excused:** Drs. Calkins, Fietelson, Ms. Greene, Drs. Muse, Rothstein

**Absent:** Dr. Srinivasan

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Dr. Grunwald called the meeting to order at 11:07 a.m.  
Quorum (10) was met

Minutes: Minutes of the September 10, 2004 meeting were presented for approval; Approved: Total: 12: Vote: For-11, Opposed-0, Abstained-1 {Mr. Koser was not present at the September meeting}

Dr. Grunwald introduced Mr. Martin Koser, new member representing the Laboratory Technician community.

**NEW PROTOCOLS:**

**F. Rouan** *Role of mesenchymal stem cells and primary keratinocytes in correcting skin defects in Epidermolysis Bullosa mice. Pre-reviewed by: Sue Gotta. (Deferred with Re-review: Total = 12; Vote: For-12, Opposed-0, Abstained-0)*

The following points must be addressed by the PI in a revised OSA-11:

Part 1, #9: PI must make mention that safety needles will be used.

PI must mention that staff who decline the Hepatitis B vaccine will sign a waiver.

Part 1, #10: PI should note that liquid waste must be inactivated with 10% bleach, then poured down the drain; no bleach other than trace amounts, and no significant amounts of liquid waste should enter the autoclave stream. Dead animals must NOT go into waste, they must be handled through the animal facility morgue.

The IBC needs to know who else is working on this project; the PI should list any Co-investigators on this protocol.

The lab will need to be inspected by the Institutional Biosafety Officer for approval at BL-2 level.

The SOPs are too general; they must be revised to reflect the specific circumstances of this project; the Institutional Biosafety Officer will work with the PI to revise the SOPs. The IBC will need a signed copy when completed.

A BBP control plan is not mentioned at all and must be included with this protocol.

**OTHER BUSINESS:**

Dr. Grunwald discussed changes in IBC website in regards to updates that he and the Ms. Gotta are working on.

Ms. Gotta presented a summary of issues regarding the IBC database and what changes are underway. The database will be redesigned to permit greater functionality and ability for cross-platform utility. To the extent



possible data from the existing database will be imported into the new database, although some of this will be done manually. We will be using the IRB database as a template, and Dr. Jack London of KCC will be providing significant assistance with the process.

Also discussed by Ms. Gotta was the research survey proposed to be sent out to the research community in order to accurately capture a more complete snapshot of research going on at TJU. Ms. Gotta passed around a copy of the proposed survey for Committee feedback. The committee raised a concern as to what level of response we would get if the survey was not totally electronic, which would take additional time and expense to develop. It was decided however to initially go on with the survey as planned, using a paper format, and that the long-term goal would be to go completely electronic.

Dr. Grunwald discussed that he has worked with Jeff IT establish an IBC Pulse Website. This website would be used to conduct IBC business, and would be a password protected on-line resource for storing and disseminating documentation relevant to the committee's business.

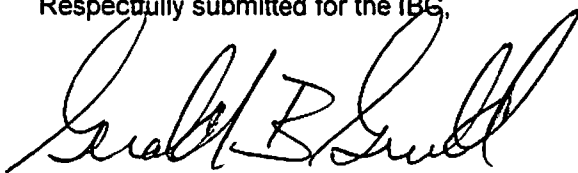
There was some discussion regarding plans for Lab Safety Training for the remainder of the year. Ms. Gotta and Mr. Steve Baker will conduct 2 more classes this year to finish out the year. Next year lab employees will still go to the classes, as it was unanimously decided by the Committee that Health Stream, while adequate for non-lab personnel, was not adequate for lab personnel. It was decided that a more detailed face-to-face training process was still needed to train laboratory personnel.

A motion was made, seconded, and approved (12-0-0) to recommend that Ms. Shaw John Sullivan of the committee's sense that Health Stream was not adequate by itself for laboratory personnel, and that the BSO training classes provided to lab personnel should continue. Ms. Shaw stated that she would be willing to send out letters to PIs stating that they need not take the Health Stream training if they take the classroom training.

Dr. Smith asked whether there was, in existence, standard TJU SOPs, and if there was, why does each PI have to provide us with SOPs. Dr. Kalf and others pointed out that the IBC needs to know that PIs have procedures that are not just general safety procedures, but that they will adapt those general procedures to their specific project. Dr. Kalf also mentioned that there had been checklists in use for PIs to acknowledge that certain areas were covered. Ms. Gotta agreed to check if these were still in use, and will circulate them to the Committee for review.

**Meeting Adjourned at 12:00 pm**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read 'Gerald B. Grunwald', written over a horizontal line.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**November 12, 2004**

**Present:** Drs. Calkins, Daviau, Flomenberg, Mr. Goll, Ms. Gotta, Drs. Grunwald, Hooper, Kalf, Mr. Koser, Dr. Maksymowych, Ms. Shaw, Dr. Smith

**Excused:** Dr. Fietelson, Ms. Greene, Drs. Jungkind, Muse, Rothstein

**Absent:** Drs. Schnell, Srinivasan

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Dr. Grunwald called the meeting to order at 11:03 a.m.  
Quorum (9) was met

Minutes: Minutes of the October 8, 2004 meeting were presented for approval; Approved: Total: 9: Vote: For-9, Opposed-0, Abstained-0

Drs Smith, Daviau and Flomenberg arrive at 11:10, vote count now 12

**NEW PROTOCOLS:**

**F. Rouan**

*Role of mesenchymal stem cells and primary keratinocytes in correcting skin defects in Epidermolysis Bullosa mice. Pre-reviewed by: Sue Gotta. (Approved with administrative changes: Total = 11; Vote: For-11, Opposed-0, Abstained-0)*

# 8: This question needs to be answered more clearly. The PI needs to discuss what the risks are. Put in a statement that those who decline the Hepatitis B vaccine will be asked to sign a declination form.

# 9: Change statement about using safety needles whenever possible, to safety needles will be used.

#10: The last 3 items here can be deleted; not necessary.

SOPs: better, but still needs some wording adjustments; the Biosafety Officer will work with PI to edit SOPs.

**P. Flomenberg**

*Human T Cell Responses to Vaccinia Vaccine (Approved with administrative changes: Total = 10; Vote: For-10, Opposed-0, Abstained-0). Dr. Flomenberg left the room for the vote.*

Please add a description of EBV, adenovirus to the abstract.

Fix lab number for Dr Eisenlorh's lab: it is now 706.

#9: Put in statement regarding documentation of vaccine declinations.

**OTHER BUSINESS:**

Ms. Gotta gave a summary report of an incident of vaccinia exposure in one of TJU's labs. A report of the incident is attached to these minutes. Ms. Gotta reported that the CDC has NO recommendations for people working with vaccinia who are NOT vaccinated. However, they recommend BL-2 conditions for people who are vaccinated.

The Committee discussed the use of vaccinia here at Jefferson, and Jefferson's Vaccinia Vaccine Policy. There was some discussion as to whether the particular exposed area would have been protected had this person been vaccinated; the exposure was to the eye area, with the eyelid being affected, not mucous membrane. One Committee member reminded us that for many years in this particular lab, there have been NO incidents of exposure, and raised the question of whether there were any statistics on how many accidents or incidents there have been; no one knew of any. Ms. Gotta related that TJU, the CDC and the PI all seemed to agree that this was indeed an accident in the truest sense. Everyone involved agreed that correct policies were in place, that it was just a case of human error.

The Committee discussed the use of vaccinia and the nature of some of the vaccinia work. In some cases, vaccinia is used to change other viruses, and that these changes would affect the effectiveness of the vaccine anyway. The double pathogen mechanism must be taken into consideration.

The Committee then discussed what kind of training is best for laboratory personnel working with vaccinia. Examples of other institutional training were cited. It was generally felt that at the very least a refresher training should be given, and that perhaps one-to-one training should be done with an explanation of the vaccine and opportunity to accept or decline immediately. It was emphatically agreed that stricter observance of filing the declination form must be in place.

Ms. Gotta stated that at this time we were waiting for some minor recommendations from the CDC, and that when those were communicated to TJU they will be put in place.

**Meeting Adjourned at 12:00 pm**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read 'Gerald B. Grunwald', written in a cursive style.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE SPECIAL MEETING TO DISCUSS VACCINIA**  
**December 10, 2004**

**Present:**     ***Judy Daviau*** (Director of Animal Resources and University Veterinarian, IBC Member)  
                  ***Phyllis Flomenberg*** (Vaccinia researcher, TJUH Infection Control Officer, IBC Member)  
                  ***Sue Gotta*** (Institutional Biosafety Officer, Vice Chair IBC)  
                  ***Gerald Grunwald*** (Chair, IBC)  
                  ***George Kalf*** (Associate Dean for Scientific Affairs, IBC Member)  
                  ***Muhammad Mukhtar*** (Infectious Diseases: representing Dr. Pomerantz's vaccinia group)  
                  ***Ellen O'Conner*** (Director, University Health Services, via conference call)  
                  ***Jolene Shaw*** (Director of Environmental Health and Safety, IBC Member)  
                  ***J. Bruce Smith*** (Assistant University Compliance Officer, IBC Member).

**Not Present:**   ***Ike Eisenlohr***  
                      ***Matthias Schnell*** (Vaccinia researcher, IBC Member).

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**Meeting called to order at 11:18 a.m.**

Participants in the meeting are members of the IBC, and invited TJU community members who work with vaccinia in some form. This meeting was held to discuss the Philadelphia Department of Health recommendations pertaining to vaccinia research and TJU, in light of the incident that occurred in Dr. Eisenlohr's laboratory on or about October 18<sup>th</sup> or 19<sup>th</sup> 2004. The recommendations were the result of the investigation performed by the Philadelphia Department of Health with assistance from the Centers for Disease Control and Prevention.

The consensus of those present is that vaccinations should remain voluntary.

Our vaccination policy is well written, but it is not well enforced. Therefore, BEFORE any employee is may begin work in a vaccinia lab, they must make an appointment with University Health Services. A physician will provide them with a packet of information on vaccinia (already exists) and inform them of the risks/benefits of the vaccine. Then, the individual may make an informed decision on whether to receive the vaccine or not. No matter their decision, they MUST sign the consent form or the declination form. This form will then be filed in the University Health Services office, with copies to be provided to the PI and the IBC, and the information will be entered into the IBC database. Without these forms on file, the individual CANNOT begin research with vaccinia.

Dr. O'Connor will speak with the emergency room physicians at both Wills Eye and Thomas Jefferson University Hospitals about the possibility of seeing an individual with a vaccinia exposure. She will include this with the annual training she does regarding needlesticks and Herpes B exposures.

Dr. O'Connor also volunteered to make up education packets about vaccinia, which an exposed individual can take with them to the emergency room.

Dr. O'Conner and Sue Gotta will modify the Herpes B wallet card to reflect the signs and symptoms of vaccinia. These will be distributed to ALL individuals who have the potential to be exposed to vaccinia. This will provide them a handy reference that can be used by their physician as to how to handle an exposure or to make a referral to the right source.

Vaccinia research will be classified as BL2 with BL3 practices. These practices are outlined in the recommendations. However, some of them will not be feasible due to the configuration of some of our lab spaces. These will be handled on a case by case basis by the IBC when vaccinia protocols are submitted to the IBC for approval.

There will be a general annual training provided by the Institutional Biosafety Officer. This training will be provided to researchers who work with vaccinia, animal care and use workers, as well as maintenance and custodial employees.


Finally, Dr. O'Conner will contact Felicia Lewis and/or Dr. Caroline Johnson (Director, Division of Disease Control, Philadelphia Health Department) to inquire about their purpose in recommending that base line serum samples should be stored for all employees working with or in labs with vaccinia present. If the purpose is to establish a titer, why can't we just titer the sample of the exposed individual and dispose of it.

Another meeting will be held to finalize the education packet, the wallet card, the definition of BL2 with BL3 practices, and the Philadelphia Health Department's response to Dr. O'Conner's question about the base serum samples.

Dr. Eisenlohr will be asked to incorporate the decisions into his SOP. With his permission, we will then make his SOP the standard for ALL vaccinia work

**Meeting adjourned at 12:00 p.m.**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read 'Gerald B. Grunwald', written in a cursive style.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/sg

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**January 14, 2005**

**Present:** Drs. Calkins, Daviau, Ms. Gotta, Drs. Grunwald, Hooper, Jungkind, Mr. Koser, Dr. Maksymowych

**Excused:** Drs. Fietelson, Flomenberg, Schnell, Smith

**Absent:** Drs. Rothstein, Ms. Shaw, Srinivasan

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Dr. Grunwald called the meeting to order at 11:10 a.m.  
Quorum (9) was met

Minutes: Minutes of the November 12, 2004 meeting were presented for approval; Approved: Total: 8: Vote: For-8, Opposed-0, Abstained-0

Dr. Grunwald discussed with the Committee the possibility of moving the venue of the next IBC meeting to the Faculty Club for a recognition luncheon for Dr. Kalf who has recently retired. The Committee was in agreement that they would like to do something like this in appreciation of Dr. Kalf's service to the IBC. Dr. Grunwald will check into details.

**NEW PROTOCOLS:**

**R. Axlerod** *A Phase III, Multi-Center, Open-Label, Randomized Study to Compare the Overall Survival and Safety of Bi-Weekly Intratumoral Administration of INGN 201 Versus Weekly Methotrexate in 240 Patients with Refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN) (T301).* **Approved: Total = 8; Vote: For-8, Opposed-0, Abstained-0**

This is the continuing review submitted simultaneously to the IBC and to the IRB. The IBC originally approved this study in conjunction with the IRB. This is the second continuing review submitted. There had been a previous adverse events that was not deemed related to the study at all.

**A. Fertala** *Growth of HTB-94 Chondrosarcoma Expressing Mutant Procollagen II in Subcutaneous Implants in Mice* **Approved with administrative changes: Total = 8; Vote: For-8, Opposed-0, Abstained-0**

Face Page: number given here is the IBC # for *this* protocol; what is needed is the unique IBC number for this *lab*

Part I, #8: this is BL-2 so there is still a risk; PI must clarify

Part I, #9: Hepatitis B vaccine must be offered and waivers kept on file.

Part I, #10: Take out boilerplate information and answer specifically for this project

Part I, #12: IBC needs to have SOPs on file

Part I, #13: IRB approval not needed

Part II, #1: not transferring drug resistant trait

Part II, #18: cDNA is a whole gene

G. Gonye

*In vivo Neuropeptide receptor expression analysis.* **Approved with administrative changes: Total = 8; Vote: For-8, Opposed-0, Abstained-0**

Part I, #8: this must be treated as BL-2 and risks described, as the cells can be infectious. You cannot say "...and has been used in a laboratory setting for many years".

Part II, #29: need more information on where the material is coming from: address

Part IV, #15: IBC is NOT approving animal work; statement will be included in IBC approval letter.

Part II: AAV is infectious even if not replication competent

Where is the animal work being done? A BL-2 lab? Where are the stereotactic injections being done?

Part II, #6: infectious virus is YES

Part II, #20: incorrectly stated that no infectious vectors used

K. Yoon

*Use of AAV for gene targeting.* **Approved with administrative changes: Total = 8; Vote: For-8, Opposed-0, Abstained-0**

Part III, #21: Please clarify why you are saying YES here

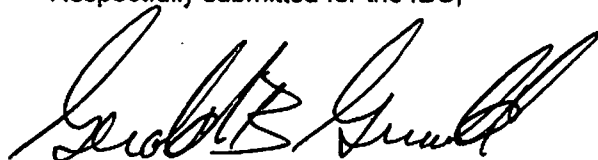
**OTHER BUSINESS:**

Arrangements will be made for bon voyage for Dr. Kalf.

There was some discussion of the feasibility/permissibility of conducting IBC meetings via teleconferencing. Dr. Jungkind spoke of a program called SKYE, a free program which allows people to talk from all over (even internationally). This is done via computer. Dr. Grunwald said the Committee would consider it.

Meeting Adjourned at 12:00 pm

Respectfully submitted for the IBC,



Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**February 11, 2005**

**Present:** Drs. Calkins, Daviau, Flomenberg, Ms. Gotta, Drs. Grunwald, Jungkind, Mr. Koser, Dr. Maksymowych, Ms. Shaw, Dr. Smith

**Excused:** Drs. Hooper, Fietelson, Schnell,

**Absent:** Dr. Srinivasan

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Dr. Grunwald called the meeting to order at 11:10 a.m.  
Quorum (8) was met

Minutes: Minutes of the January 14, 2005 meeting were presented for approval; Approved: Total: 9; Vote: For-9, Opposed-0, Abstained-0

Mr. Koser inquired as to whether there was any information/update on the vaccinia situation concerning the CDC's recommendations for Dr. Eisenlohr. Ms. Gotta reported that Dr. Eisenlohr is working to accomplish the CDC requirements. The Committee decided it would be best to have Dr. Eisenlohr present for any future discussions by the Committee concerning the vaccinia situation.

**NEW PROTOCOLS:**

**M. Pacifici** *Mechanisms of Synovial Joint Formation.* **Provisionally Approved: Total = 10; Vote: For-10, Opposed-0, Abstained-0, pending the following clarifications:**

Part I, pg 2, #8 Please do not use "totally safe"; please change to "relatively safe"  
Part IV will be needed for the mouse work  
Please provide a vector map  
Correction must also be sent to Dr. Judy Daviau of IACUC  
Approval letter from IBC will state that IBC is NOT giving approval for animal work

***Dr. Smith leaves at 11:25, vote count now 9***

**Y. Sykulev** *Detection and targeting of infected cells with TCR-like antibodies.* **Deferred: Total = 9; Vote: For-9 Opposed-0, Abstained-0**

Part I, pg 1, #1: what form of toxins are being used? Tell us if it is whole or fragment. From the answer to #16, Part II: looks like it is active.

Part I, pg 1, #4: Answer here is "no"; but in #12 Part I it is stated, "the protein will be concentrated and stored at 4c". Will you be concentrating the toxin or not? If yes, how? What precautions will be taken to prevent aerosols?

Part I, pg 1 #6: why are the experiments being done in 352F JAH? If you have mice there, same containment practices as for rabies must be used. These toxins however do not require BL-3 containment.

Part I, pg 2, #10: is 10% bleach enough to inactivate the toxin?

Part I, pg 2, #12: this is not an SOP; it is a protocol. What is required here is a procedure for how materials need to be handled for safety. Also must include what to do in case of a spill.



Part I, pg 3 #13: Please remove IRB control number; it is not applicable to this project.

Part II, pg 1, #1: PI mistakenly changed this question instead of #11; please change #1 back to "no" and change #11 to "yes".

Part II, pg 4, #28: What is being put into the mouse: a vector containing genes encoding the toxin/antibody conjugate? If it is a vector, then this answer would remain "yes", if using toxin-antibody conjugate, the answer should be changed to "no".

Part IV, pg 1, #9 & 12: will toxin be excreted by animals? What precautions need to be taken to protect animal care workers.

#### **OTHER BUSINESS:**

Dr. Jungkind described for the Committee a phone call he received from someone identifying himself as a Special Agent from Federal Aviation Association. This special agent then proceeded to ask Dr. Jungkind several questions related to one of his shipments of infectious material. The special agent described that he was doing a quality check to see if the phone number provided on the dangerous goods declaration worked and whether or not he would be able to reach someone who could answer questions concerning a spill. While the agent assured Dr. Jungkind that he had answered all questions properly, he questioned whether he would have the same experience if he had called at 2 a.m.

The special agent then began to describe to Dr. Jungkind a company that provides 24-hour service for situations such as this. Dr. Jungkind researched the company and feels that for the modest fee involved, it would serve TJU well to subscribe to the service. This company would then become the "contact" in an emergency situation. They would have all the pertinent information on our shipments on file and would be able to respond no matter what time of day.

Dr. Jungkind agreed that his lab would pick up the cost of subscribing to this service, if the University would in turn supply the second line of defense phone number. Ms. Gotta and Ms. Shaw will look into what the expectations are for this back-up number and get back in touch with Dr. Jungkind

**Meeting Adjourned at 12:10pm**

Respectfully submitted for the IBC,



Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**March 11, 2005**

**Present:** Drs. Calkins, Daviau, Flomenberg, Ms. Gotta, Drs. Grunwald, Hooper, Mr. Koser, Dr. Maksymowych, Schnell, Ms. Shaw,

**Excused:** Drs. Fietelson, Smith

**Absent:** Dr. Srinivasan

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Dr. Grunwald called the meeting to order at 11:03 a.m.

Quorum (8) was met

Dr. Grunwald welcomed Dr. Ike Eisenlohr to the meeting. Dr. Eisenlohr wished to address the Committee regarding the recent vaccinia exposure in his lab. Dr. Eisenlohr was invited to speak concerning this incident, and discussion ensued. The Committee discussed some options for modifications to protocol—i.e., fitted double gloves.

**NEW PROTOCOLS:**

**J. Rabinowitz**      *Analysis of Mixed AAV Serotype and Epitope Modified Virions for Cardiac Transduction. Approved: Total = 10; Vote: For-10, Opposed-0, Abstained-0, pending the following clarifications:*

The Committee considered whether AAV should be considered a pathogen due to the possibility of insertion. They agreed however that these AAV vectors did not fit the definition of a pathogen.

Page 3: Change statement "we have a tube holder which should reduce frequency" to "we have a tube holder to prevent needle sticks".

Part 2, #1: change answer to "no".

Part 4, #2, 3: this is not completed; PI needs to fill in what he is injecting into mice and what it does.

**J. Das-Sarma**      *The role of neurological communication in the pathogenesis of Mouse Hepatitis Virus. Deferred: Total = 10; For-10, Opposed-0, Abstained-0*

Part I, pg. 2, #8: it is stated that "it is not airborne pathogen". The Committee feels that this is an incorrect statement as mouse Hepatitis Virus is an airborne pathogen.

Part I, pg. 2, #12: The Committee feels this response needs to be expanded. Written procedures for the experiments not only in the lab but also in the animal facilities should be provided. ALL precautions which will be taken to see that this virus is not accidentally spread to the mouse colony must be included.

Part IV, pg. 1, #9: mouse Hepatitis Virus is known to be excreted in urine, feces, expired air, and skin. This answer must be changed.

The Committee needs to know where the virus is coming from. Will it be grown in the PI's lab or obtained elsewhere?

All personnel will have to be trained for procedures for the animal BL-3 lab. PI must contact Dr. Daviau to arrange for this training.

The lab facilities at 300 JHN will need to be inspected by the Biological Safety Officer; Ms. Gotta will contact PI and make arrangements for inspection.

***Drs. Schnell (conflict of interest) and Flomenberg leave; vote count = 8.***

**Y. Sykulev**

***Detection and targeting of infected cells with TCR-like antibodies. Provisionally Approved; Total = 8; For-8, Opposed-0, Abstained-0.***

The Committee would like clarification of questions #11-13 of Part IV. Is the PI saying that there are NO special precautions to be taken at all or that there are no additional precautions above and beyond the standard BL-3 precautions already in place?

Ms. Gotta will contact Dr. Schnell about the use of Diphtheria toxin.

Dr. Daviau will check the IACUC approval to see if the animal work has been approved.

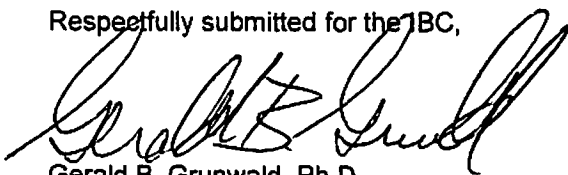
**OTHER BUSINESS:**

Ms. Gotta discussed a survey that was sent to her from the CDC. This survey is being administered by the CDC for the purpose of evaluating vaccinia safety practices and vaccination guidelines for laboratory workers who handle the live virus. The survey is intended, according to the CDC, to evaluate the knowledge, attitudes, and practices of laboratory personnel with respect to smallpox vaccination and safety procedures.

While the CDC representative who sent the survey assures that there would be no link to individuals answers to the institution, the Committee feels that there many privacy issues that must be addressed if TJU participates in the survey. Ms. Gotta will contact the appropriate TJU officials to determine the next step and an appropriate response.

**Meeting Adjourned at 12:25pm**

Respectfully submitted for the IBC,



Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**June 10, 2005**

**Present:** Drs. Calkins, Daviau, Feitelson, Ms. Gotta, Drs. Grunwald, Hooper, Mr. Koser, Dr. Maksymowych, Drs. Muse, Schnell, Ms. Shaw, Dr. Smith

**Excused:** Dr. Rothstein

**Absent:** Dr. Jungkind

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Dr. Grunwald called the meeting to order at 11:03 a.m.

Quorum was met

Dr. Grunwald welcomed Loretta Kelly to the IBC; Ms. Kelly is a new member representing interests of the surrounding community.

**Minutes:** Minutes for March 11, 2005 meeting were reviewed and approved

**NEW PROTOCOLS:**

**B. Dietzschold** *Development of a Recombinant Nipah Virus Vaccine for Wildlife. Provisionally Approved: Total = 11; For-11, Opposed-0, Abstained-1 [Schnell, he is a participant on the grant] pending the following:*

The Committee feels that the recovery of the virus should not be done at TJU; only make the construct here, then ship to Canada for making the virus. Dr. Schnell discussed that he has talked with Dr. Dietzschold concerning this, and although the protocol as presented seems like the work would be done at TJU, that has actually changed. If viral work is done here, it would be under BL-3.

Part I, pg. 2 no IRB needed; besides this is not an IRB number

Part II, #8: answer should be "yes"

Part II, #28: answer should be "yes"

Part IV, #14: answer should be BL-3

Part IV, #10: should be "unknown"

On SOPs, do not list names (they are outdated anyway); just put in that staff are immunized and regularly screened.

Clean up should be with 10% bleach followed by 70% EtoH for surfaces  
On page 4 of SOP, separate out procedures for skin splashes v. work space contamination.

In Part IV, G: revise the vaccinia policy as the vaccine and/or boosters are not required at TJU.

**J. Das-Sarma**

*The role of neurological communication in the pathogenesis of Mouse Hepatitis Virus. Deferred: Total = 13; For-13, Opposed-0, Abstained-0*

**General Discussion:**

The Committee feels that there are still more clarifications needed. Dr. Daviau stated that she is getting no feeling that this researcher understands the severity of not letting her staff handle these mice. While there is no great concern for the people, the implications of contamination in the mouse colony is devastating

The Committee feels strongly that this is potentially extremely damaging to the mouse colony and that extreme care must be emphasized in order to let this work proceed. The Committee wondered whether there was another way to accomplish this research? Dr. Schnell suggested that we contact Dr. Weiss at Penn to get a sense of what they do since they have been working with this; he agreed to make contact with her.

There must be clear documentation that this work must not begin until such time that all the Committee's concerns are addressed. The Committee wants DETAILED SOPs for this project!

Dr. Daviau stressed that Office of Animal Research will set strict requirements for this work.

**Specific Comments:**

Part I, #4: no response to "do you concentrate the agent of material"; in the preamble it is clearly stated that stocks of the viruses will be generated in the laboratory "as per requirement" and purified (Part IV #3). Does this not entail concentration of filtering the virus?

Part I, #5: how are the viral stocks made?

Part I, #8: The statement "mouse hepatitis virus is only infectious to mice and it is (an ) airborne pathogen" downplays the gravity of the risk of infection to other mice. Mouse hepatitis virus is highly infectious to mice and is an airborne pathogen. Not only laboratory safety precautions but special handling of the infected mice and all material they come in contact with is necessary to minimize the risk of the spread to other mice.

Part IV, #3: the response indicates purified diluted virus is used to infect yet the response to Part I #5 suggests that the virus must be propagated in vivo (since no cell line are used). These responses seem at odds with the response of Part I #4.

Part IV, #9: responses to the amounts of agent excreted/secreted in expired air and skin must be made.

Part IV, #12: special procedures for handling these mice are necessary to minimize the chance of infecting other mice. Each of the sections must be answered in detail how the mice, cages, bedding, bottles, etc. will be handled to prevent spread of the virus.

Part IV, #13: describe the procedures for disposing of animal carcasses; these will contain highly infectious virus

**SOPs:**

It is not sufficient to state that the CDC/NIH guidelines for BL-2 and BI-3 will be followed. A brief synopsis of the relevant guidelines should be provided.

A final concentration of 10% bleach should be used to decontaminate surfaces followed by 70% alcohol to clean the surfaces.

An absorbent towel can be placed on the cabinet surface to contain spills. If it is soaked in disinfectant it will not be absorbent and a spill can spread. If a spill occurs then disinfectant is poured over the absorbent towel.

70% ethanol is not a suitable first line disinfecting and can fix material to the surface. A final concentration of 10% bleach should be used first and then cleaned up with alcohol.

The procedure for packaging solid waste detail before removal from the laboratory for autoclaving should be stated.

Where are cultures to be used in this work? No cells are noted in OSA-11. Contaminated specimens must be placed in double-leak proof containers for transport and, where appropriate, the route used for transport should be approved.

When decontaminating a spill, clean up material etc should be double-bagged and decontaminated by autoclaving or incineration (where appropriate).

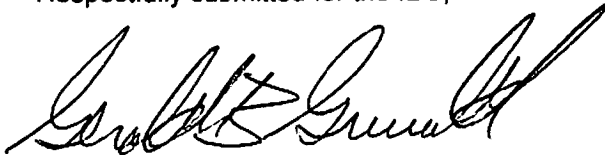
**OTHER BUSINESS:**

Ms Gotta discussed the continuing updating process of the IBC files and database; progress is being made, and Office of Research Administration is working with us in identifying research that the IBC needs to be aware of.

Ms. Gotta also reported that TJU is now using Chem-Tel as the 24-hour emergency contact number when shipping infectious substances. She has a copy of the procedures for anyone who needs them.

**Meeting Adjourned at 12:25pm**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read 'Gerald B. Grunwald', written in a cursive style.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**August 19, 2005**

**Present:** Drs. Calkins, Daviau, Flomenberg, Ms. Gotta, Drs. Grunwald, Hooper, Jungkind, Mr. Koser, Dr. Rothstein, Ms. Shaw, Dr. Smith

**Excused:** Dr. Feitelson, Ms. Kelly, Drs. Maksymowych, Schnell,

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Dr. Grunwald called the meeting to order at 11:15 a.m.

Quorum was met

Minutes of 6/10/05 Meeting Approved 12-0-0

**NEW PROTOCOLS:**

**J. Das-Sarma**      *The role of neurological communication in the pathogenesis of Mouse Hepatitis Virus. Deferred, pending further clarifications: Total = 12; For-10, Opposed-0, Abstained-0*

**General Discussion:**

There remains a general concern, and it is unclear from the SOP what, if any, post –infection analysis will be done on mouse cells or tissues from infected mice, for the purpose of analyzing the presence of virus or viral RNA, frozen tissue preparation for antigen expression studies, and histochemical and pathological analysis. Also, none of the above procedures are addressed in the OSA-11. The protocol, OSA-11 and SOP need to be clarified to address these issues, especially the use of virus in the lab as opposed to the animal facility.

**Specific Comments OSA-11:**

**Part I: Item 5:** Sentence states “*Primary neural cells will be isolated from neonatal mice and will be used to infect viruses*”. The meaning of this sentence is not clear. Please clarify. Also, please indicate if there is any intention in the protocol to return infectious material to the laboratory.

**Part IV, Item 12:** In the first paragraph, please delete sentence “*Hands should be washed before and after each animal cage handling*”.

In second paragraph, please delete sentence “*There is an absolute minimal frequency of changing bedding, but it typically varies from twice to thrice in a week. In general, enclosures and accessories such as tops should be sanitized at least once every two weeks*”.

In third paragraph, delete sentence “*Infectious animal carcasses can be incinerated on site*”. Replace with statement “*Infected animal carcasses can be autoclaved prior to disposal*”.

**SOP for Animal Facility:**

**Handling of Animals:** In first paragraph, delete sentence "*Hands should be washed before and after each animal cage handling*". Also, in sentence "*Dissected material for disposal will be sealed in double plastic bags, properly labeled and incinerated*", change "incinerated" to "autoclaved".

**Disposal of Animal Bedding:** Delete sentences "...but it typically varies from twice to thrice in a week. In general, enclosures and accessories such as tops should be sanitized at least once every two weeks".

In the following sentence, "*Infectious animal carcasses will be sealed in double bags, properly labeled and incinerated*", change "incinerated" to "autoclaved".

Likewise, two paragraphs below, in sentence, "*Dissected material for disposal will be sealed in double plastic bags, properly labeled and incinerated*", change "incinerated" to "autoclaved".

**OTHER BUSINESS:**

This Committee has previously discussed having a more detailed policy for certain work at the BL-2/3 level. This work would include for example, work with Lentiviral vectors. A document has been developed by Ms. Gotta, which with the Committee's approval will be distributed and posted on the Web. This document will serve as a reference for when the Committee calls for a protocol to be given approval at the BL-2 level but with BL-3 practices.

The Committee has been asked to review this DRAFT document and provide feedback directly to Ms. Gotta.

**Meeting Adjourned at 12:10pm**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read "Gerald B. Grunwald".

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw



**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**September 9, 2005**

**Present:** Drs. Calkins, Daviau, Ms. Gotta, Drs. Grunwald, Hooper, Jungkind, Ms. Kelly, Mr. Koser, Dr. Maksymowych, Ms. Shaw,

**Excused:** Drs. Feitelson, Flomenberg, Rothstein, Schnell, Smith

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Dr. Grunwald called the meeting to order at 11:15 a.m.

Quorum was met

**NEW PROTOCOLS:**

**S. Joseph** *Assembly & Turnover of IP3 Receptors; IBC Control #05.011. Approved pending modifications: Total = 10; For-10 Opposed-0, Abstained-0*

**General Comments:**

This investigator is currently BL-1 and is seeking BL-2 approval. An inspection of this laboratory space will need to be done in order for the work to proceed.

**Specific Comments OSA-11:**

Part I, #8: delete the statement "...(*associated with human disease which is rarely serious and for which preventative or therapeutic interventions are often available*)"

Part II, items 4 & 5: the answer here needs to be changed to "no"

**Specific Comments SOPs**

SOPs need to be expanded to include a statement that no sharps will be used.

**D. Herrick** *Regulated c-myc Destabilization During Differentiation; IBC Control #05.012. Approved pending modifications: Total = 10; For-10, Opposed-0, Abstained-0*

**General Comments:**

This protocol is approved pending receipt of, and approval by the BSO, of the laboratory's SOPs.

**Specific Comments OSA-11:**

Part I, #10: first sentence needs to be re-phrased to clarify solid waste disposal.

In regard to personal protective equipment, change sentence to read "*lab coats are to be worn*"; (not *encouraged*).

Part I, #12: the statement "*All procedures will be carefully performed to minimize the creation of splashes or aerosols*" is too general. What specifically do you do to minimize splashes or aerosols?

Add in that 811 must be dialed in the event of a spill.

Add in a statement that Employee Health will be contacted in the event of an accident.

**M.L. Chu**

*Ullrich Syndrome: Pathogenesis and Therapies*; IBC Control #05.013.  
**Approved pending modifications: Total = 10; For-10, Opposed-0, Abstained-0**

**General Comments:**

This protocol is approved pending receipt of and approval by the BSO of laboratory SOPs and a re-inspection of the lab.

**Specific Comments OSA-11:**

Part I, #9: simply state that no prophylaxis is available or needed; move the first sentence of #9 to last line of #8.

What is being done with data from PCR? How does this enhance the safety of the experiment? This should be scratched.

Part I, #10: material does not have to be autoclaved, can go right into red boxes

**OTHER BUSINESS:**

The Committee discussed the BL-2/3 document distributed at last meeting. There have been several changes made to the document to correct spelling errors. Committee members will forward any further comments to Ms. Gotta.

A discussion ensued regarding the use of safety needles while doing certain animal injections. In the opinions of most researchers who do these injections, using safety needles is just not practical. There is a very high failure rate for these devices, and often times the researcher must defeat the safety mechanism in order to make the injection.

Ms. Shaw stressed the importance of TJU being in compliance with OSHA regulations, the importance of documentation in this kind of situation, and suggested that several types of devices may need to be tried in order to find one that works. The Office of Environmental Health & Safety can perhaps work with TJU purchasing agents to find something that works better.

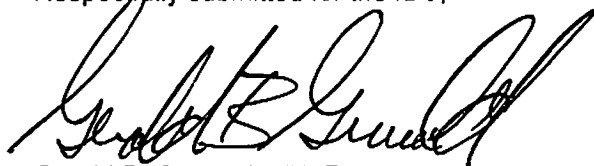
Dr. Grunwald advised the Committee that submission of changes to a previously deferred protocol had reached his desk, but not in time for this meeting, and stated that he would circulate those responses. The comments at this time from the Committee include concern over whether the investigator will be able to maintain BL-3 practices in a shared laboratory space, and how the instruments used for the BL-3 protocol would be cleaned so as not to contaminate others' work.

Dr. Daviau raised the issue of what happens, or is supposed to happen, when a researcher leaves the institution. [REDACTED]

[REDACTED], Ms Gotta mentioned that the issue is on an agenda for a scheduled meeting with the Vice President for Research that she and the Director of Office of Scientific Affairs will be attending.

**Meeting Adjourned at 12:24pm**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read 'Gerald B. Grunwald', written in a cursive style.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**October 21, 2005**

**Present:** Drs. Calkins, Daviau, Feitelson, Flomenberg, Ms. Gotta (Vice Chair), Drs. Hooper, Jungkind, Mr. Koser, Drs. Maksymowych, Ms. Shaw, Drs. Rothstein, Smith

**Excused:** Dr. Grunwald (Chair), Ms. Kelly, Drs. Muse, Schnell

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Ms. Gotta called the meeting to order at 11:07 a.m.

Quorum was met

**NEW PROTOCOLS:**

**J. Flynn** *Roles of COX-1, -2, and -3 in the Endothelial Cell Response to Bacterial Endotoxin. (Control Number: 05.014) Approved: Total = 12; For-12 Opposed-0, Abstained-0*

#13: answer here really should be n/a; this can be done administratively and the PI will be notified that it was changed.

**K. Alugupalli** *Interaction of Borrelia hermsii with host immune system. (Control Number: 05.015) Administratively Approved: Total = 12; For-12 Opposed-0, Abstained-0*

Dr. Daviau noted that the cages for these animals will be kept in the BL-3 suite; the animal protocol is pending.

SOP is needed

Approval pending inspection by BSO

Part IV, page 2, #8: please acknowledge risk of needle stick while withdrawing syringe from animal.

Part IV, page 2, #11: syringe procedure needs to be clarified; are they re-capping safety needles?

**K. Sharma** *TGF-beta Signaling in Diabetic Kidney Disease. (Control Number: 05.016). Deferred: Total = 12; For-12 Opposed-0, Abstained-0*

Part I needs questions 6-13 answered

Needs Part IV filled out

Part III, page 1, #27: release of DNA to environment not answered

Part III, page 1, #30: needle sticks should dealt with via University Health Services, not the ER

C. Adams

*Smart Substrates for New Generation of Implants. (Control Number: 05.017).*  
**Administratively Approved: Total = 12; For-12 Opposed-0, Abstained-0**

There is a contradiction between the OSA-11 and the SOP as to the disposal of the needles/syringes. The whole unit should be put into the sharps container.

The use of glass spreaders is not recommended. The PI may contact Dr. Jungkind to discuss alternatives to using these glass spreaders.

There is no mention of downstream analysis of biofilm on inserted hips centrifugation.

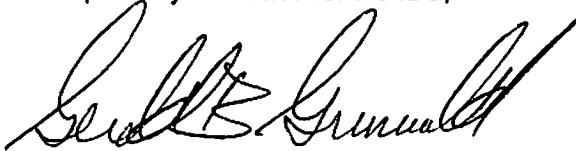
**OTHER BUSINESS:**

Minutes of 8/19/05 meeting approved: **Total = 12; For-12 Opposed-0, Abstained-0**  
Minutes of 9/9/05 meeting approved: **Total = 12; For-12 Opposed-0, Abstained-0**

Ms. Gotta gave the Committee an update Dr. Das Sarma's protocol. Dr. McKenzie has reviewed all documents. There have been phone calls back and forth to Abigail Smith from Penn. The Penn facility has NO shared equipment, and they are VERY confident in their PI. She advised that while the safeguards being required by the IBC are good, it only takes one human error to ruin it all. Dr. McKenzie has talked to Dr. Rostami to say he will not forbid this research, but wanted to know how critical the work was for this specific researcher. Dr. Das Sarma has contacted Dr. Grunwald and has stated that she was told that she could not do the work.

**Meeting Adjourned at 11:59am**

Respectfully submitted for the IBC,



Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

GBG/taw

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**November 11, 2005**

**Present:** Drs. Calkins, Daviau, Grunwald (Chair), Hooper, Jungkind, Ms. Kelly, Mr. Koser, Drs. Maksymowych, Rothstein, Schnell, Smith

**Excused:** Drs. Feitelson, Flomenberg, Ms. Gotta, Dr. Muse, Ms. Shaw

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Dr. Grunwald called the meeting to order at 9:45 a.m.

Quorum was met

Minutes of the October 21, 2005 meeting approved: **Total = 11; For-11 Opposed-0, Abstained-0**

**NEW PROTOCOLS:**

**M. Mukhtar** *Impact of Glycemic Variations on the Transmigration of Immune Cells Across the Blood Brain Barrier. (Control Number: 05.020) Deferred: Total = 11; For-11 Opposed-0, Abstained-0*

The reviewer and the Committee both felt that this protocol would be best separated into 3 smaller projects.

The Committee needs to see a protocol for the SNU vector work.

Protocols and SOPs will need to be written for each project.

**D. Woulfe** *Akt-regulated pathways in platelet function-MSCV. (Control Number: 05.018) Deferred: Total = 11; For-11 Opposed-0, Abstained-0*

*Akt-regulated pathways in platelet function-myrAkt. (Control Number: 05.019) Deferred: Total = 11; For-11 Opposed-0, Abstained-0*

Part 1 must be completed for both.

The Committee needs to see more information on the vector.

**OTHER BUSINESS:**

Dr. Grunwald discussed the possibility of changing the meeting time due to ongoing conflicts for several members of the Committee.

As had been discussed by Ms. Gotta last meeting, Dr. Grunwald advised the Committee that the work proposed by Dr. Das Sarma will not, at this time, be carried out at Jefferson.

**Meeting Adjourned at 11 am**

Respectfully submitted for the IBC,

A handwritten signature in black ink, appearing to read "Gerald B. Grunwald". The signature is fluid and cursive, with the first and last names being more prominent.

Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

**GBG/taw**

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**December 16, 2005**

**Present:** Drs. Daviau, Flomenberg, Ms. Gotta (Vice Chair), Drs. Grunwald (Chair), Hooper, Ms. Kelly, Mr. Koser, Dr. Maksymowych, Ms. Shaw, Dr. Smith

**Excused:** Drs. Feitelson, Muse

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Dr. Grunwald called the meeting to order at 9:45 a.m.

Quorum was met

Minutes of November 11, 2005 meeting approved: **Total = 10; For-10, Opposed-10, Abstained-0**

**NEW PROTOCOLS:**

**M. Mukhtar**      *Impact of Glycemic Variations on the Transmigration of Immune Cells Across the Blood Brain Barrier. (Control Number: 05.020)* **No vote; this work is not within this Committee's purview**

The Committee does not need to review this at this time; however, at some time in the future when this investigator wants to use the spleen necrosis, we will need an OSA-11.

An OSA-14 needs to be submitted to the appropriate Committee for this work.

**K. Sharma**      *TGF-beta Signaling in Diabetic Kidney Disease. (Control Number: 05.016)*  
**Administratively Approved: Total = 10; For-10, Opposed-10, Abstained-0**

Part I, #7: both items here should be left blank; BL-3 training does not pertain to this protocol

Part I #10: only solid waste should go into the red bag/box system; please modify, stating the solid wastes will go into red bag/box system and sharps will go into the sharps container.

Part I #11: please delete "closed container" and replace with "primary container within a sealed, leak-proof, secondary container".

Part I #13: IRB approval not applicable, please change to N/A

Part II, #5: DNA is not coming from risk group 2 organism; please change answer to "no"

**D. Woulfe**      *Akt-regulated pathways in platelet function-MSCV. (Control Number: 05.018)*  
**Administratively Approved: Total = 10; For-10 Opposed-0, Abstained-0**

Part I #5: check off "human" and "other"; HEK293T cells are human cell line



Part I #8: please include the possible risks associated with using these cells. Include that Hepatitis B vaccination will be offered to those working with the cells.

Part I #9: safety glasses are not necessary since work will be done in a hood

Part I #9: separate out the disinfecting of surfaces from the disinfecting of liquids; OK to disinfect surfaces with 10% bleach, but not OK to add 10% to liquids.

Part I #13: please add the IRB control number for this project

Part II #6: please answer

Part II #31: discrepancy here: first says no sharps being used, but then talks about possible needle sticks. Please clarify. Also, do not call 911; the individual would need to go to University Health Service or the ER (after hours).

**D. Woulfe**

*Akt-regulated pathways in platelet function-myrAkt. (Control Number: 05.019)*  
**Administratively Approved: Total = 10; For-10 Opposed-0, Abstained-0**

Part II #8: this should be "yes"; by generating a transgenic animal, you are working with a whole animal. This change, with permission of PI may be made by administrative staff.

**OTHER BUSINESS:**

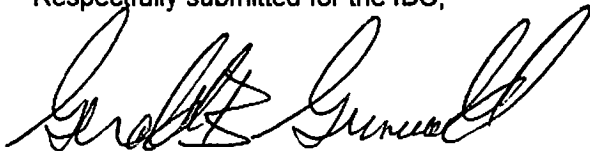
Dr. Grunwald reported that in polling the Committee, it seems that a 10 a.m. meeting time would resolve several scheduling conflicts for Committee Members. A new meeting time of 10 a.m. has been set.

A schedule of 2006 Calendar year meetings was distributed.

Dr. Hooper discussed a rabies exposure that occurred in his lab over the Thanksgiving Holiday.

**Meeting Adjourned at 11:05 am**

Respectfully submitted for the IBC,



Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

**GBG/taw**

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**January 13, 2006**

**Present:** Drs. Calkins, Daviau, Flomenberg, Ms. Gotta (Vice Chair), Drs. Grunwald (Chair), Hooper, Ms. Kelly, Mr. Koser, Dr. Maksymowych, Schnell

**Excused:** Drs. Feitelson, Jungkind, Muse, Rothstein, Ms. Shaw, Dr. Smith

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Dr. Grunwald called the meeting to order at 10 11 a.m.

Quorum was met

Minutes of December 16, 2005 meeting approved: **Total = 10; For-10, Opposed-0, Abstained-0**

**NEW PROTOCOLS:**

**R. Pestell** *Initiation and Maintenance in Mammary Tumorigenesis (IBC #06.001).* **Deferred: Total = 10; For-10, Opposed-0, Abstained-0.**

Abstract must be rewritten in lay language

Part I: Adenovirus must be listed in #1-4

Part I #8: first paragraph needs to be deleted; the dangers of working with human cell lines must be addressed

Part I #9: please include that Hepatitis B vaccination will be offered to those working with cell lines

Part I #10: in the last paragraph, please include information on how you will minimize the risks involved in this work

Part I #11: please specify that double containment will be used to carry around

Part I #12: make this section specific for this work, but please provide the IBC with a general SOP for your lab

Part II #7: are you really using a helper virus? Please clarify.

Part II #8: the answer here conflicts with the answer given in Part I #6, please clarify

Part II #28: we will need to know where getting the material; although it is answered in #13, it needs to be repeated here.

Part II #19-25: better description of vectors is needed; the Committee also needs to see vector maps. Please specify safety issues related to vector

Part IV #9-12: need better answers; no animal protocol?

**R. Pestell**      *CYCLIN D1 Function in Prostate Cancer (IBC #06.002)*  
*Caveolin-1 and Cyclin D1 in Mammary Tumorigenesis (IBC #06.003)*  
*Regulation of Cyclin D1 Expression (IBC #06.004)*

The Committee feels that these protocols can be combined into one protocol. Remove animal statement from abstract to combine.

**N. Sang**      *Molecular Mechanisms Underlying Neoplasm Formation and its Therapies (IBC #06.005)*  
**Deferred: Total = 10; For-10, Opposed-0, Abstained-0.**

**Meeting Adjourned at 11:05 am**

Respectfully submitted for the IBC,



Gerald B. Grunwald, Ph.D.  
Chair, Institutional Biosafety Committee

**GBG/taw**