



RUSH UNIVERSITY
COLLEGE OF NURSING
RUSH MEDICAL COLLEGE
COLLEGE OF HEALTH SCIENCES
THE GRADUATE COLLEGE

Kate-Louise Gottfried, JD, MSPH
Senior Director, Office of Research Integrity

Edward Hammond
The Sunshine Project
1920 Stuart Street
Berkeley, CA 94703

November 6, 2006

Dear Mr. Hammond:

The Rush University Medical Center (RUMC) Institutional Biosafety Committee (IBC) submits its approved meeting minutes pursuant to your request of October 12, 2006. Approved Minutes from May 2003 to September 2006 are attached as a single pdf file. Minutes from the October 31, 2006 meeting are not yet approved. You will also receive a hard copy of the IBC minutes.

The RUMC biological safety program, the Biological Safety Officer (BSO), and the IBC fall under the purview of the Office of Research Integrity. Future correspondence regarding IBC minutes pertaining to rDNA protocols should be directed to the BSO:

Ed R. Blazek, Ph.D
Biological Safety Officer
600 S. Paulina Street
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Chicago, IL 60612
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Sincerely,


Kate-Louise Gottfried

Cc: E. Blazek
A. Virdi

Rush University Medical Center--Institutional Biosafety Committee Minutes

This document contains all approved minutes of IBC meetings after 1 May 2003 to 6 November 2006.

Company names, external protocol numbers, and agent trade names of investigational agents have been visibly redacted to protect proprietary commercial interests, consistent with the NIH OBA (Patterson) memo of 5/14/04. These redactions are identified as to type: [Company Name], [Protocol No.], [Agent Trade Name].

Abbreviations used in Minutes:

AAV	adeno-associated virus
BBPT	Bloodborne Pathogen Training
BSL1	Biosafety Level 1
BSO	Biological Safety Officer
cAMP	3'-5'-cyclic adenosine monophosphate
CDC	Centers for Disease Control
CRC	(Rush) Comparative Research Center
DA	dopaminergic (neurons)
EGFR	epidermal growth factor receptor
FDA	Food and Drug Administration
GDNF	glial cell-derived neurotrophic factor
GTP	guanosine-5'-triphosphate
HGF	hepatocyte growth factor = hepapoietin A
HIF1 α	hypoxia-inducible factor 1 alpha
HIV	human immunodeficiency virus
HPR1	heparanase-1
HSV	Herpes simplex virus
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IL-13	Interleukin-13 (as protein not DNA)
IRB	Institutional Review Board
MPTP	1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine
NGF	nerve growth factor
OBA	Office of Biotechnology Activities
ORA	(Rush) Office of Research Affairs
RAC	(Federal) Recombinant DNA Advisory Committee
rDNA	recombinant DNA
VEGF	vascular endothelial growth factor

Meeting Minutes May 15, 2003

Present: J. Bremer, Ph.D. L. Brodsky, M.P.H. T. Green W. Knudson, Ph.D. J. Kordower, Ph.D. S-P. Kwan, Ph.D. J. Oswald, D.V.M. M. Peeples, Ph.D. S. Pur, R.N., B.S.N. D. Simon, M.D.	Absent: D. Clark, Ph.D., <i>ex officio</i> P. Cronic, Ph.D.
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Meeting called to order at 11:15 a.m.

1. New committee member introduced: E. Sondergaard
2. Approval of minutes from March 20, 2003 meeting: MOTION to approve, seconded, motion passed.
3. Expedited approvals since March 20, 2003:

Investigator	ORA#	TITLE
J. Bremer	98111701	Virology Quality Assessment Program
M. Peeples	02052301	Translation Regulation in Sendai Virus

4. Approved after PI made changes requested by the IBC:

Investigator	ORA #	TITLE
J. Kordower	03042204	Neurturin Gene Therapy in a Rat Model of Huntington's Disease
J. Qiao	03010303	Regulation of Rho GTPases by cAMP-dependent Protein Kinase: Protective Mechanism Against Endothelial Barrier Dysfunction

D. Simon entered the room

5. A "Code Orange" plan for internal preparedness plan is being developed. This plan will be discussed at the next meeting.
6. The Center for Disease Control Select Agents list was presented. This list has been added to the end of the IBC application form.

S. Pur entered the room

7. Select agents and toxins destruction form: need to add a line for quantities. Rush investigators previously registered with the CDC were removed from the registry according to these criteria:
 - (a) they are doing clinical work that does not need to be reported
 - (b) they possess less than a specified quantity of an agent or toxin
 - (c) they have destroyed or used up the agent or toxin

This information was provided to the CDC in writing.

Do the clinical laboratories need to report select agents and toxins? CDC guidelines require clinical labs to report possession of select agents and toxins, even if it is for diagnostic purposes only. Also, the CDC requires that the agent or toxin be destroyed within a certain period of time. If it is being stored for longer than the given period, the CDC must be assured that it will be stored in a locked and secure facility, and that the staff has Department of Justice security clearance to handle these materials. Dr. M. Hayden has a clinical lab and, therefore, should be notified of the notification/reporting regulations set forth by the CDC. Are there special methods for destruction? Each material is unique and must be identified and destroyed appropriately.

8. New/Tabled IBC Applications

Investigator	ORA #	TITLE	
J. Snell	pending	Protocol [Protocol No.]: A phase II multi-center, double-blinded, placebo-controlled trial of [Agent Trade Name] in intermittent claudication secondary to peripheral arterial disease	
C. Sortwell	01071203	Angiogenic Enhancement of Dopamine Neuron Grafts	
W. Knudson	95101801	CD44-Mediated Catabolism of Hyaluronan by Chondrocytes	

W. Knudson Study Discussion:

The procedure for the study was described. Lentivirus delivered from the company cannot propagate. Everything seems to be addressed correctly on the application. The Lab Rules attached need to be investigator's own. For question #13 insert "Fill out employee health injury form." (Employee Health requires a form before seeing the employee.) Soap and water for needle sticks are better than 70% alcohol.

W. Knudson left the room

MOTION: Conditional approval pending changes was moved, seconded, and passed.

N.B. The recommended changes were made and final approval was granted on May 19, 2003

W. Knudson entered the room

J. Snell Study Discussion:

This is a Phase II, human study. Plasmid suppresses angiogenic factors in those with Peripheral Arterial Disease. Phase I has already been done. The product was tolerated well; only local bruising at site of injection was noted. Phase I study continues for long-term toxicity. The concern is that prior subject screening may miss a cancer, and this product may enhance tumor growth. The Office of Biotechnology and RAC had no comments. The study is appropriately categorized as BSL1. Bloodborne pathogen training needs to be updated for three people involved in the study. Little systemic distribution of the study agent has been observed in animals. Its efficacy in human studies is not known. The consent form is appropriate. This seems to be a reasonable study from an IBC standpoint. Study requires 22-28 injections—staff needs to wear eye protection and gloves. Appendix M needs to be updated for Rush—site-specific information required (M2b5a-M2b5b). In case of accidental needle sticks or exposure, there is a possibility of spreading. The PI is asked to make the following changes:

- Changes site-specific answers in Appendix M
- Wear eye protection and gloves when giving injections
- Update BBPT dates
- Improve statement of procedures for accidental needle sticks
- Question #12: recommend 10% bleach concentration or Virex 256

- Question #13: wash with soap and water, then fill out accident report and go to Employee Health Services

MOTION: Conditionally approved pending recommended changes, seconded, and passed. Recommended changes were submitted, and final approval was granted on May 27, 2003

C. Sortwell Study Discussion:

Rush IACUC has already approved this study. This group studies Parkinson's disease. The therapeutic principle is that cellular grafts could help overcome the disease. In this study, they are adding a component to increase vascularization, hoping it will prolong viability of the graft. Biosafety Category IID1 is appropriate. Initial transfection may end up with some HSV (10^{-6} probability). C. Sortwell will be the only person handling the vector—her BBPT needs to be updated (last renewal 7/2002). Of the others listed on the grant application, who would need BBPT? HSV does not infect rats; it will not be transmitted through the experimental host animal. It is only a concern for those doing the initial injection. PI needs to include/change:

- Question #11: disposal by Stericycle. The Tech 2000 facility has separate contract for waste disposal; thus, Rush Biohazard is NOT responsible.

T. Green will review and clarify waste disposal section. Ultimately, the PI is responsible for proper waste disposal. Do the people who are handling HSV prior to the injection require BBPT? No, by the time the staff is preparing to inject, the HSV is already gone. Environmental services does not service Tech 2000—remove from question #12 and the safety sheet.

- For waste disposal, autoclaving is not necessary—red Biohazard bag disposal is okay.
- Occupational Safety also needs to be removed from the application.
- In case of exposure, employee needs to fill out form and report in person to Employee Health Services, not just call them.

MOTION: Approve by Chairperson pending changes: moved, seconded, and passed. Recommended changes were submitted, and final approval was granted on January 5, 2004.

9. Do routine vector studies require full committee review or expedited review? These decisions were reached by the IBC.
- Routine work with infectious agents—expedited.
 - Human or animal studies—full committee review.
 - Cell cultures, defective vectors, etc.—expedited.
 - Anything new—Chairperson can send to committee if necessary.
 - Virus vectors—Chairperson's decision to send to full committee or expedite.
 - Defective virus vectors *in vitro*, and adenovirus—Chairperson's decision to send to full committee, expedite, or consult with committee members and/or experts.
 - Routine defective virus vector genes—expedited.

We should actively promote IBC awareness.

MOTION: Approve procedures as stated: moved, seconded, and passed.

Meeting adjourned at 12:15pm. Minutes submitted by G. Ahuja.

Meeting Minutes January 22, 2004**Present:**

E. Sondergaard
 L. Brodsky, M.P.H.
 T. Green
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M.
 M. Peeples, Ph.D.

Absent:

D. Clark, Ph.D., *ex officio*
 P. Cronce, Ph.D.
 J. Bremer, Ph.D.
 S. Pur, R.N., B.S.N.
 A. Tenorio, M.D.

Meeting called to order at 11:10 a.m.

1. New committee members: N. Lurain, Ph.D. and A. Tenorio, M.D. Introduced: N. Lurain.
2. Updated NIH Guidelines distributed.
3. Approval of minutes from May 15, 2003 meeting: **MOTION: approve, seconded, motion approved**
4. Expedited Since May 15, 2003

Investigator	ORA#	TITLE
M. Emborg	02072206	Lentiviral Delivery of GDNF-TET to aged Nonhuman Primates
M. Emborg	03031902	Lentiviral Delivery of GDNF 3 Months Post MPTP Treatment
R. Loeser	03092505	Dysregulation of the Chondrocyte in Aging Cartilage
G. Spear	03052002	Activation of Innate Immunity by Filovirus Glycoproteins
G. Spear	03010201	Cell Surface Interactions Important for HIV Infection
T. Glant	04011903	Mouse Link Proteins: Expression and Function
W. Knudson	04011904	Hyaluronan Fragment Signaling and Cartilage Degeneration

5. Approved after PI made changes requested by the IBC

Investigator	ORA #	TITLE
W. Knudson	95101801 Amendment	CD-44 Mediated Catabolism of Hyaluronan by Chondrocytes
J. Snell	03050502	[Protocol No.]: A phase II multi-center, double-blind, placebo-controlled, trial of [Agent Trade Name] in subjects with intermittent claudication secondary to peripheral arterial disease
C. Sortwell	01071203	Angiogenic Enhancement of Dopaminergic Neuron Grafts

6. Do animal studies need to go to full committee review? Only those animals being injected with rDNA require full-committee review. Transfection into eukaryotic cells may be expedited by the chairperson. Revise May 2003 minutes to clarify these points. The ORA Proposal Routing Form should include a checkbox for "IBC Exempt".
7. Is it convenient for everyone if we move the meetings to the fourth Thursdays instead of the third Thursdays? Decide later via email poll.

8. Amendment Form: Amendments require detailed explanations of waste disposal, needle-sticks, etc. A short version of the original form may not be sufficient. PI should be required to use the original application with a checkbox for "amendments". Application should be appended to include policy numbers. Policy numbers will be added with the help of T. Green. **MOTION: revise original application so that it can be used to submit amendments, seconded, and passed.**
9. Announcing new chairperson: W. Knudson, Ph.D. Who should be the co-chair? Co-chair will be assigned at a later date.
10. Internal Response Plan introduced by T. Green will be discussed at the next meeting.

W. Knudson left the room

11. Select Agents and Toxins Destruction form has been revised to include a line for quantities as stated in the May 2003 minutes.

12. New/Tabled IBC Applications

Investigator	ORA #	TITLE	
C. Sortwell	03052703	Evaluation of Hypoxia in Grafted DA Neurons	

Discussion: Is investigator using virus vectors? Yes, but it is not infectious to animals. *In vitro*, it can be infectious for a single cycle, but no infectious agent is being injected into the animals.

Ask PI to make the following changes:

- Question #11 - check off "Rush Biohazard Removal" for any additional solid waste.
- Question #13 – Hamilton syringe is okay, but are any other syringes being used? If so, describe precautions being taken, and needle-stick procedures to be followed.

MOTION: chairperson shall approve pending changes, seconded, and passed.

Meeting adjourned at 12:20pm. Minutes submitted by: G. Ahuja, MPH

Meeting Minutes March 25, 2004**Present:**

T. Green
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M.
 E. Sondergaard
 A. Tenorio, M.D.

Absent:

L. Brodsky, M.P.H.
 D. Clark, Ph.D., ex officio
 P. Cronce, Ph.D.
 J. Bremer, Ph.D.
 S. Pur, R.N., B.S.N.

Meeting called to order at 11:09 a.m.

1. Introduction of T. Hale (G. Ahuja's replacement).
2. Approval of minutes from January 22, 2004 meeting: **MOTION: moved, seconded, and passed.**
3. Expedited Since January 22, 2004

Investigator	ORA#	TITLE
NONE		

4. Approved after PI made changes requested by the IBC

NONE		

5. New/Tabled IBC Applications

Investigator	ORA #	TITLE
Z. Arvanitakis	04032903	A Phase I, Dose-Escalating Study to Assess the Safety and Tolerability of [Agent Trade Name] Adeno-Associated Virus (AAV)-based, Vector-Mediated Delivery of Beta Nerve Growth Factor (NGF) in Subjects with Mild to Moderate Alzheimer's Disease. [Protocol No.]
G. Schaer	00021004	A Multi Center, Randomized, Double-Blind, Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered Via [Company Name] Stiletto Endocardial Injection Catheter pVGL1 (VEGF2) (placebo, 20, 200, or 800 µg) In Patients With Class III or IV Angina With An Option For Patients To Receive Active Treatment At One Year If They Experience A Treatment Failure

6. Member stated that there is no other potential danger besides the normal risk that the adeno-associated virus would cause in the Z. Arvanitakis study.
7. Member noted that the NIH already approved this study, and recommends approval provided that investigator changes intervals from once every month to once every 3 months as RAC had requested, and provided blood borne pathogen training of staff is completed.

A. Tenorio entered the room at 11:30am

8. Member poses question about operational policies used on page 11, stating that it should be changed to Operational Policy 203, 147, and 277. Member also states that on page 12 (item 13), the Operational Policy should be changed to 191.
9. Member moves to approve this study pending: Blood Borne Pathogen training, new changes in operational policies, and RAC request amended in Rush's file for this study. Motion is seconded, no discussion, motion carried.

Introductions are done again since Dr. A. Tenorio has arrived.

10. Second study discussed, G. Schaer. Member had questions about changes in protocol (i.e., lab location and microorganisms used).
11. Member asks whether the IBC should ask for consent forms.
12. Member asks "Do we (IBC) consistently ask for IRB forms for all studies"?
13. Member states that previously IRB consents were not required.
14. Member states that on page 9 item #11 the item needs to be destroyed before they remove it. Autoclaving would be sufficient.
 - a. Member moved that we approve this study pending revisions to Biohazards and RAC amendment letter, motion seconded, no discussion, motion carried.
 - b. Member asks "is there a co-chair"?
15. Member suggests Dr. J. Bremer as co-chair.
16. Member points out that Dr. J. Bremer is sometimes absent and that co-chair needs to be there when chair is not.
17. Member wants to know if we need a named co-chair, or can we have an *ad hoc* co-chair chosen from among attendees?
18. Decided that there will be an *ad hoc* and Dr. W. Knudson will appoint people as needed.
19. Should we (IBC) make copies of applications, or should the PI?
20. Member states PI should be responsible for copies; that is consensus of members.
21. Member: IBC shouldn't review an application unless copies are attached.
22. Member suggests sending out a broadcast email introducing new members and # of application copies to be submitted.

Meeting adjourned at 12:01pm. Minutes submitted by T. Hale.

Meeting Minutes May 27, 2004**Present:**

J. Bremer, Ph.D.
 P. Cronce, Ph.D.
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M
 A. Tenorio, M.D.

Absent:

L. Brodsky, M.P.H.
 D. Clark, Ph.D., ex officio
 E. Sondergaard
 S. Pur, R.N., B.S.N.
 T. Green

Meeting called to order at 11:10 a.m.

1. Approval of minutes from March 25, 2004 meeting. **Motion: moved, seconded, motion approved**

2. Expedited Since March 25, 2004

Investigator	ORA#	TITLE
L. Valentino	04011604	Induction of Hemophilic Synovitis in Mice Deficient in Osteopontin
L. Valentino	Not Assigned	Factor IX Replacement Therapy to Prevent Hemophilic Synovitis in Factor IX Deficient Mice

3. Approved after PI made changes requested by the IBC

Investigator	ORA#	TITLE
Z. Arvanitakis	04032903	A Phase I, Dose-Escalating Study to Assess the Safety and Tolerability of [Agent Trade Name] Adeno-Associated Virus (AAV)-based vector- Mediated Delivery of Beta Nerve Growth Factor (NGF) in Subjects with Mild to Moderate Alzheimer's Disease. [Protocol No.]
G. Schaer	00021004	A Multicenter, Randomized, Double-Blind, Dose Ranging Placebo Controlled Study Evaluating Defined Doses of Percutaneously Delivered Via [Company Name] Stiletto Endocardial Injection Catheter Pvg.1 (VEGF2) (placebo,20, 200, or 800ug) In Patients With Class III or IV Angina With An Option for Patients To Receive Active Treatment At One Year If They Experience A Treatment Failure

4. New/Tabled IBC Applications

Investigator	ORA #	TITLE
R. Byrne	04040803	A Phase III Randomized Evaluation of Convection Enhanced Delivery of [Agent Trade Name] Compared to Gliadel Wafer with Survival Endpoint in Glioblastoma Multiforme Patients at First Recurrence [Trial Name, Protocol No.]
G. Spear	04031901	A Murine Model of HIV Genital Tract Infection

Discussion

5. Committee discusses if this study will even need IBC approval because everything was being handled at the company [Company Name]. IL13 is a protein, rather than a recombinant DNA, which removes the possibility of genetic transmission. All protocols seemed to be very "clean."

6. A proposal is made that a letter be written to the IRB stating that the study does not need IBC approval, and to thank the IRB for the opportunity to review the study. The IBC will welcome all future reviews when the IRB is in doubt about whether a study needs IBC approval.
7. It is agreed that the research staff of this study needs Blood Borne Pathogen Training.

Discussion of G. Spear Study:

Committee discusses whether Dr. G. Spear turned in revised form. It is decided that Dr. G. Spear will need to go to the website and get the online version of the recently updated IBC rules hand book.

J. Bremer entered the room at 11:25am

A member of the committee asks if Section IIID box D3 applies to this study. The IBC decided that Section IIID box D4 should be checked off. Another member asks if the study should be tabled?

8. Committee decides against tabling the application. They will grant it provisional approval, provided that the Principal Investigator submits revisions that were requested: Check appropriate box in application form, complete entire application.
9. Motion for provisional approval made: committee member asks "what is the endpoint Dr. G. Spear is looking for?" Another member replies that investigator wants to see if mice will become infected.
10. Previous motion for provision approval: seconded and passed.

Discussion of J. Zhang Study:

1. This study was previously approved under Dr. M. Peebles' chairmanship. Committee chair recommends administrative approval since Dr. J. Zhang is just resubmitting it for grant approval.
2. Community member expresses concern that project description is written in very scientific language and needs to be simplified.
3. Chairman agrees to address this when he gives administrative approval.
4. Committee notes that their Blood Borne Pathogen Training has expired and their Biohazard Hood certification is overdue.
5. Motion for conditional approval pending update of Blood Borne Pathogen and Biohazard Hood re-certification was seconded and passed.
6. The chairman of the committee asks Dr. J. Bremer whether there is a reason for the submission of 12 copies of the IBC application, but not its supplemental information?
7. Committee discusses the possibility of there being a submission of 12 copies of the supplemental information and not just 2. Committee decides not to decide on it today.
8. There is discussion on the operational procedures being revised and also the route to access the IBC applications on line.
9. Member has further concerns about the R. Byrne study and would like to review it more before writing the letter saying that it will not need IBC approval. The question of concern is whether toxins fall under the jurisdiction of the Institutional Biosafety Committee.
10. The date of the November meeting needs to be changed due to the holiday.
11. Committee agrees to meet the Thursday before Thanksgiving.

Meeting adjourned at 12:40 pm. Minutes submitted by T. Hale, B.S.

Meeting Minutes October 21, 2004**Present:**

J. Bremer, Ph.D.
 L. Brodsky, M.P.H.
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 E. Sondergaard
 A. Tenorio, M.D.

Absent:

D. Clark, Ph.D. ex officio
 P. Cronce, Ph.D.
 T. Green
 J. Oswald, D.V.M.
 S. Pur, R.N., B.S.N.

Meeting called to order at 12:07 p.m.

Approval of minutes from May 27, 2004 meeting. **Motion for provisional approval pending the correction of Dr. J. Bremer's last name and E. Sondergaard and T. Green being absent: moved, seconded, and passed. 5 yes, 0 no.**

Chairman would like to know if committee member S. Pur is still a part of the committee or would she like to offer someone else from her department to take her place on the committee.

1. Expedited Since May 27, 2004

Investigator	ORA#	TITLE
T. Glant	89050101	Auto Immune Progressive PolyArthritis
B. Cole	04090201	Tissue Engineered Human Neocartilage to Repair Goat Full Thickness Cartilage
T. Collier		The Trophic Factor Pleiotrophin: Neuroprotection and graft-derived reconstruction of the nigrostriatal system
Y. Zhang		Gene Therapy for Intervertebral Disc Degeneration
F. Huang		Lysophosphatidylcholine promotes monocyte transmigration by a novel specific G protein-coupled receptor expressed by endothelial cells
G. Schaer	0021004	A Multicenter, Randomized, Double-Blind, Dose Ranging Placebo Controlled Study Evaluating Defined Doses of Percutaneously Delivered Via [Company Name] Stiletto Endocardial Injection Catheter Pvg.1 (VEGF2) (placebo, 20, 200, or 800ug) In Patients With Class III or IV Angina With An Option for Patients To Receive Active Treatment At One Year If They Experience A Treatment Failure

Discussion: Chairman explains that all of the expedited studies that gained approval involved all drugs that were commercially available.

2. Approved after PI made changes requested by the IBC

Investigator	ORA#	TITLE
J. Zhang*	00061205	Cbl-b in cell activation and autoimmunity
G. Spear	04031901	A Murine Model of HIV Genital Tract Infection
L. Valentino*	01012604	Proto-oncogene expression in hemophilic synovitis

*Consistent with established IBC procedures for low-risk protocols, the changes were requested by the IBC chair as the representative of the committee.

3. New/Tabled IBC Applications

Investigator	ORA #	TITLE
R. Byrne	04040803	A Phase III Randomized Evaluation of Convection Enhanced Delivery of [Agent Trade Name] Compared to Gliadel Wafer with Survival endpoint in Glioblastoma Multiforme Patients at First Recurrence [Trial Name, Protocol No.]
J. Snell	Not assigned	A Phase II Double-Blind, Randomized, Placebo-Controlled Study To Assess The Safety And Efficacy Of [Agent Trade Name] to Improve Perfusion In Critical Leg Ischemia

Discussion of R. Byrne Study:

4. Chairman discusses and passes out a copy of the letter that he sent to the IRB regarding the decision that Dr. R. Byrne's study did not need to receive IBC approval
5. Committee agrees that the letter is appropriate and would like to know if the study eventually gained IRB approval. IBC coordinator informs the committee that the study did receive IRB approval.
6. Member reiterates his concern that the *E. coli* may multiply and produce toxins.
7. The chairman discusses his conversation with Dr. D. Clark about the concerns that the committee had and informed the committee that he and Dr. D. Clark discussed the option of forming another committee that would look at studies with drugs that are not FDA-approved.
8. The chairman addresses the issue that the IBC will continue to review all studies to make the determination whether it needs IBC approval or not.
9. Chairman states if there are no studies to go to full committee on next month, the November 21st 2004 meeting will be cancelled.

J. Snell Study:

Description of study: The description of study was given by the primary reviewer. This is a study of the [Agent Trade Name] gene transfer product commonly known as "HGF Plasmid". It is sponsored by [Company Name]. The product is distributed to 25 sites and only 4 subjects are enrolled here at Rush; hence Rush plays a small part in this large-scale study.

Discussion: A committee member questions whether routine Rush Biohazard disposal is sufficient? The consensus is that their biohazard disposal method is suitable. It is good practice to destroy biological activity before putting it on public roads. Since the transfer method is syringe, putting them into the proper biohazard waste container is fine.

2. Member asks if the lab rules are sufficiently detailed to approve. Chairman explains that lab rules were modified explicitly for this study, and that in chair's judgment, they are okay.
3. Member would like to know if Appendix M has been modified to explain this particular study at Rush or are they using a general Appendix M for all the sites of this study.
4. Reviewer of this study explains she did not see anything wrong or unusual with this study's appendix M, and it was tailored to Rush's specific site.
5. Member would like to know if there is an informed consent. There is an informed consent document, but the IBC does not require it to be submitted for review.

6. The primary reviewer's comments are as follows: "PI needs to update Blood Borne Pathogen training and degradation agent such as UV light needs to be used to inactivate DNA".

7. Chairman gives the comments of the second reviewer's revisions, because this reviewer has not yet arrived to the meeting. "Section 8C should describe E. coli strain not plasmid, and section 12 should use DNA degradation agent such as UV light or DNA lamp".

There is a motion made to provisionally approve the study pending revisions, and any further comments from secondary reviewer. Motion seconded and passed: 5 yes, 0 no, 0 abstentions

N. Lurain entered the room at 12:39 p.m.

1. Committee informs N. Lurain of the provisional approval of Dr. J. Snell's study and hands N. Lurain the letter that the chairman wrote to the IRB concerning Dr. R. Byrne's study.

2. Chairman discusses Dr. J. Kordower study that received provisional approval through expedited review, and brings to light the issue that the IBC does not have an official amendment form. That the current procedure is for the investigator to send a letter of the changes they would like to make.

3. Committee discusses new way to submit amendments to IBC applications.

A. A. Tenorio entered the room at 12:44 p.m.

4. Committee member suggests that to submit an amendment to a study, one should also submit the original approved application, an amendment letter describing the changes, and a new copy of the application form with the changes updated. If the experimental protocol itself is changed, a new protocol should be submitted. **Motion is made for the above suggestion; seconded, and passed. 7 yes, 0 no, 0 abstentions**

New Business:

1. The committee discusses the fact that there is no co-chair for the IBC committee and in the case that Dr. W. Knudson is not around to sign off on approval letters there needs to be a co-chair assigned to the committee or a designated committee member authorized to sign authorization letters.

2. Committee discusses and decides to let the primary and secondary reviewer be authorized to sign an IBC authorization letter if the chairman is not available.

Meeting adjourned at 12:59 pm. Minutes submitted by: T. Hale, B.S.

Meeting Minutes March 24, 2005

Present:

J. Bremer, Ph.D.
T. Green
W. Knudson, Ph.D.
S-P. Kwan, Ph.D.
N. Lurain, Ph.D.
J. Oswald, D.V.M.
E. Sondergaard
A. Tenorio, M.D.

Absent:

D. Clark, Ph.D. (*ex. officio*)
L. Brodsky, M.P.H.
S. Pur, R.N., B.S.N.

1. The meeting was called to order at 11:08 am. Introductions were made with a brief explanation of what each individual's role is on the IBC as well as within the institution.
2. The minutes from the October 21, 2004 meeting were approved: Motion: J. Oswald; Seconded: T. Green
Vote: For: 6; Against: 0; Abstain: 0
3. The members concurred with the expedited approvals since October 21, 2004:

Investigator	ORA#	TITLE
G. Maki	03111107	Evaluation of NK cells as a means of immunotherapy for hematological malignancies
W. Knudson	04011904	Hyaluronan Signaling and Cartilage Degeneration

4. There were no applications that were approved after PI made changes requested by IBC.
5. There were no new/abled IBC applications.
6. Old Business:
 - A. The IBC discussed whether there were any necessary changes to the existing IBC application or annual review forms. It was noted that V. Berry will send annual renewal notices to PI's beginning April 1, 2005.
 - B. The IBC discussed the type of applications within IBC jurisdiction. The IBC concurred that we may need to institute a specific submission form for use/handling of human tissue of unknown infectious status. Member stated that he will converse with Dr. D. Clark about this issue.
 - C. The IBC concurred that an ORA number must be assigned to an IBC application before it is considered by the Committee. Member stated that he is certain that an ORA number will be assigned to an application before it is received by V. Berry and forwarded to any IBC member.
 - D. The IBC concurred that only the local generation of transgenic animals requires an IBC submission, not simply the purchase and/or use of such animals generated elsewhere.
 - E. The IBC concurred that PI's should submit 2 copies of an IBC application for preliminary review. It was stated that if additional copies are required, V. Berry will contact the PI and make this request.
 - F. It was noted that the selection of the appropriate box on the application in question 4 is difficult for PI's to assess and complete. The IBC concurred that a PI completing the application must consult the NIH guidelines / website when completing the application. In addition, member stated that he will provide examples for investigators to assist in completing the application.

- G. The IBC concurred that any IBC member can review applications to decide whether full committee review is warranted and may sign IBC correspondences, including approval letters, in Dr. W. Knudson's absence.
 - H. The IBC concurred that Drs. W. Knudson and J. Oswald should generate appointment letters for IBC members and develop a 2-year rotation for IBC membership.
7. New business:
- A. The resignation of Dr. P. Cronic was discussed. Member stated that he would inquire as to whether any of the IACUC community members would consider IBC membership and that he would discuss a pipeline for community IBC members with Dr. D. Clark.
 - B. The issue of V. Berry providing administrative support to the IBC was discussed.
8. Meeting adjourned at 11:55 am: Motion: Dr. J. Oswald; seconded: Mr. T. Green
Vote: For: 8; Against: 0; Abstain: 0

Minutes submitted by V. Berry.

Meeting Minutes May 26, 2005**Present:**

M. Bowman, Ph.D.
 L. Brodsky, M.P.H.
 D. Clark, Ph.D. (*ex officio*)
 T. Green
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 J. Oswald, D.V.M.
 E. Sondergaard

Absent:

J. Bremer, Ph.D.
 N. Lurain, Ph.D.
 S. Pur, R.N., B.S.N.
 A. Tenorio, M.D.

The meeting was called to order at 11:15 am

1. Dr. W. Knudson opened the meeting by asking that everyone new to the IBC provide brief introductions. Dr. J. Oswald introduced M. Bowman, Ph.D. from the University of Illinois at Chicago.
2. The minutes for the March 24, 2005 IBC meeting were approved. Motion: Dr. J. Oswald; Seconded Dr. M. Bowman, and passed. Vote: For: 6; Against: 0; Abstain: 1
3. Dr. D. Clark was the next to speak. Dr. D. Clark began by explaining his role in attending the IBC meeting and future plans for the IBC's handling of applications in which only the handling of human tissues is conducted. The IBC concurred that with the assistance of Research Administration and Compliance, a Biosafety Officer (BSO) should be hired. The BSO would be responsible for assuring that Blood Borne Pathogen Training and training in the disposal of these materials is complete and appropriate. The responsibilities of the BSO would also included conducting inspections of and monitoring activities in the laboratories. Dr. D. Clark also explained that there will be a new Associate Provost for Research, Dr. J. Mulshine who should address whether the handling of human tissues falls under the jurisdiction of the IBC. Dr. M. Bowman explained how UIC handles these types of applications.
4. **Expedited Review and Approval Since March 24, 2005**

Investigator	ORA#	TITLE
R. Bakay	02101004	Stem Cells in CNS Transplantation
M. Delcommenne	05042801	Recombinant Human Antibodies Targeting Heparan Sulfate Motifs Specific of Multiple Myeloma Cells- Investigation of their Anti-Myeloma Tumoricidal Effects.
E. Mufson	05032502	Transgenic Mouse Models of Alzheimer's Disease
J. Qiao	05010601	PKA-induced Phosphorylation of GDP Dissociation Inhibitor: Role in Endothelial Barrier Function Regulation
E. Rios	02011102	Skeletal Muscle Ca ²⁺ Release Control Inside the SR
G. Spear	04082003	Murine Model of STD-enhanced HIV Transmission
L. Valentino	05032503	Effect of Recombinant Factor VII Prophylaxis on Hemarthrosis

5. New/Tabled IBC Applications for Full Committee Review

Investigator	ORA#	TITLE
G. Schaer	05051102	A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center, Dose-selection of Ad2/Hypoxia Inducible Factor (HIF)-1 α /VP16 in Patients with Intermittent Claudication-Walk Study [Protocol No.]
J. McAuley	05051002	Phase I open Label Study to Evaluate the Safety at Tolerability of recombinant HIV +.

Investigator	ORA#	TITLE
L. Verhagen	05033101	A Phase I, Open-Label Study of [Agent Trade Name] Adeno-Associated Virus Serotype 2 (AAV2)-Neurturin(NTN) to Assess the Safety and Tolerability of Intrastriatal Delivery to Subjects with Idiopathic Parkinson's Disease [Protocol No.]
J. Bremer	05050601	Generation of Standards for Use with Molecular Assays.

Discussion of ORA# 05051002 (J. McAuley Application)

Reviewer stated that this application describes a phase I clinical trial to determine the safety of recombinant DNA vaccines utilizing a modified Vaccinia virus and a modified fowl pox virus. He stated that the vaccines will express the “gag” and other proteins of the HIV virus in hopes of generating an antibody response to these viral proteins in sixteen HIV-positive, non-AIDS patient volunteers. A major question regarding this application was whether it required review by the federal Recombinant DNA Advisory Committee (RAC). After extensive discussion, the IBC concurred that this application is in fact exempt from RAC review. It was noted that the modified Vaccinia virus vaccine has been administered to over 100,000 human patients as a smallpox vaccine and there were a small number of adverse events in the trial in which this vaccine was administered. The IBC concurred that the PI of this application should be specific as to the personnel who will be administering the trial vaccines and to assure that these individuals will have the opportunity to be vaccinated against Vaccinia and that routine medical surveillance will be provided for these individuals. The IBC concurred that the disposal method and potential spill procedures for the trial vaccines should be more specific. In addition, the specific area in which these trial vaccines will be administered must be identified and post-vaccination clean-up procedures for this area must also be explained in the application. Lastly it was noted that there were several other errors in completing the application which must be corrected/clarified prior to approval of this application. After some additional discussion, a motion was made, seconded and passed to table this application until the PI has responded to the IBC's concerns and until the next regularly scheduled IBC meeting.

Motion to Table: Dr. W. Knudson; Second: Dr. J. Oswald; Vote: For: 6; Against: 0; Abstain: 1

Discussion of ORA# 05051102 (G. Schaer Application)

The primary reviewer of this application was absent from the meeting. The secondary reviewer stated that this application described the administration of a recombinant DNA, replication-defective adeno-associated viral vector clone inserted in a cell line to generate blood vessels in a group of 300 patient volunteers. It was stated that [Company Name] would like to test this therapy in four different doses. The secondary reviewer discussed her comments which included that the PI must provide a map of the construct. The IBC concurred that not all personnel to be involved in the project had completed up-to-date blood-borne pathogen training and that the containment level should have been indicated as BL2 but was labeled BL1. The IBC concurred that lab rules for the project must be provided. There were other criticisms, including that the IBC should inquire whether each lot of the final product is tested for recombination events *in vitro*. The IBC concurred

that the PI must also provide a copy of the initial consent document for patient volunteers enrolling in the trial as well as the specific RAC comments provided to [Company Name]. The IBC concurred that errors in the application occurred on pages 6, 7 and 8 and must be clarified/corrected. After some additional discussion a motion was made, seconded and passed to table this application until the PI has responded to the IBC's concerns and until the next regularly scheduled IBC meeting.

Motion to Table: Dr. J. Oswald; Second: Mr. T. Green; Vote: For: 7; Against: 0; Abstain: 0

Discussion of ORA# 05050601 (J. Bremer Application)

Reviewer provided a brief overview of the application and discussed the primary reviewer's comments. The IBC concurred that the PI must assure that the biosafety cabinet listed in item #6 on page 6 has been certified and that the PI must list HIV-1 as a human hazard in item #9A on page 7 of the application. In addition, the IBC concurred that the risk group classifications, III for HIV-1 and II for Sindbis virus, should be recorded in item #8D on page 7 of the application. Lastly, the IBC concurred that the answer to item #9B on page 7 should be changed from "not applicable" to "no" After some additional discussion, a motion was made, seconded and passed to approve this application pending the submission of the clarifications discussed above.

Provisional Approval Motion: Dr. J. Oswald; Second: Dr. M. Bowman; Vote: For: 7; Against: 0; Abstain: 0

Discussion of ORA# 05033101 (L. Verhagen Application)

Reviewer stated that this application described the administration of the neurturin (NTN) gene incorporated into an adeno-associated virus serotype 2 [Agent Trade Name] in hopes of protecting and possibly generating dopamine-producing neurons initially in four patient volunteers with Parkinson's disease. He stated that this project is a safety and preliminary efficiency study of [Agent Trade Name] that will utilize two doses. Reviewer provided a brief overview of the application which he stated was complete and thorough, in addition, he lead a detailed discussion of the RAC review comments provided to the PI and the PI's response to the RAC. The IBC concurred that the PI should submit for review by the IBC, the modified informed consent document as requested by the RAC. In addition, the IBC concurred that the PI must confirm that appropriate members of the research team have completed the Rush "shipment of dangerous goods" training. After some additional discussion, a motion was made, seconded and passed to approve this application pending the submission of the clarifications discussed above.

Provisional Approval Motion: Dr. J. Oswald; Second: Mr. T. Green; Vote: For: 6; Against: 0; Abstain: 1

6. New Discussion

Dr. W. Knudson stated that he would like additional IBC members to review protocols, including a virologist and other faculty members that he would like to recruit. The IBC concurred that he should do so.

7. Meeting adjourned at 1:10 pm. Motion: Dr. W. Knudson; Seconded: Dr. J. Oswald; Voted: For: 7; Against: 0; Abstain: 0

Minutes submitted by: V. Berry

Meeting Minutes July 28, 2005**Present:**

J. Bremer, Ph.D.
 M. Bowman, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M
 A. Tenorio, M.D.
 L. Brodsky, M.P.H.
 T. Green
 E. Sondergaard
 W. Knudson, Ph.D.

Absent:

S. Pur, R.N., B.S.N
 D. Clark, Ph.D.

The meeting was called to order at 11:10 am

1. The minutes for the May 26, 2005 IBC meeting were approved with the following corrections: the responsibilities of the Biosafety Officer should include "...conducting inspections of and monitoring activities in the laboratories" in item #2. Various typographical errors should be corrected. Motion: E. Sondergaard; Seconded: Dr. S-P. Kwan; Vote: For: 8; Against: 0; Abstention: 0

2. Dr. W. Knudson noted that V. Berry has left Rush for a new work opportunity and that D. Haywood would be administrating the IBC until the vacant position is filled.

The IBC concurred with the expedited review and approval since May 26, 2005.

	ORA#	TITLE
J. Kerns	05060312	Repair of the Partial Nerve Lesion: an Experimental Model

9. The IBC concurred with the applications approved after PI made changes requested by the IBC:

Investigator	ORA #	TITLE
J. Bremer	05050601	Generation of Standards for Use with Molecular Assays
L. Verhagen	05033101	A Phase I, Open-Label Study of [Agent Trade Name] (Adeno-Associated Virus Serotype 2 (AAV2)-Neurturin (NTN) to Assess the Safety and Tolerability of Intrastriatal Delivery to Subject With Idiopathic Parkinson's Disease [Protocol No.]

10. New/Tabled IBC Applications for Full Committee Review

Investigator	ORA#	TITLE
G. Schaer	05051102	A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center, Dose-selection of Ad2/Hypoxia Inducible Factor (HIF1 α /VPI6) in Patients with Intermittent Claudication-Walk Study [Protocol number]

Discussion of ORA# 05051102

It was the consensus of the Committee that the PI had done a good job in responding to the concerns and clarifications requested by the IBC in the letter dated June 2, 2005. The PI provided a map of the construct, lab rules, the patient consent document and the correspondence from the RAC to the sponsor, in addition to responses to the other clarifications requested. Flu-like symptoms are the most common SAE reported to IBC when utilizing an adeno-associated viral vector. The Laboratory Safety Officer will assure that all personnel in the laboratory will complete the required HES Laboratory Safety training module. Any approval letter of this application should include a reminder to the PI to submit a final copy of the study patient consent document to the OBA. After some additional discussion, a motion was made, seconded and passed to approve this application.

Motion to Approve: Dr. S-P. Kwan; Second: Dr. N. Lurain; Vote: For: 8; Against: 0; Abstention: 0

11. The IBC concurred with the notification of annual renewals.

Investigator	ORA #	TITLE
F. Cohen	82051941	Molecular Biophysics and Physiology

12. Old Business

Additional members of the IBC are being sought. The names of 5 potential members were discussed. Drs. W. Knudson and J. Oswald will follow-up with these individuals to determine whether they would be willing and eligible to serve on the IBC. The term of service for IBC members remains undecided.

13. New Business

Review of UIC's "Human Gene Transfer Review" Form. IBC members reviewed the "Human Gene Transfer Review" form used by the UIC IBC to document their review of such IBC applications. There was considerable discussion over whether review of the patient consent document should be reviewed by the IBC or simply requested and maintained on file. There should be an ability to identify IRB correspondence to the PI that would significantly impact the review of the consent document by the IBC. After some additional discussion, the IBC concurred that Drs. W. Knudson and J. Oswald should revise the document in question to reflect Rush IBC concerns and re-present the document to the IBC for further consideration.

Release of IBC Minutes to Non-members. Dr. W. Knudson had received a request by a PI to obtain the minutes from an IBC meeting at which his/her IBC application was discussed. Dr. W. Knudson corresponded with Dr. D. Clark, the Director of Research Compliance, who noted that although it seems warranted for the IRB and IBC to share minutes, it may not be appropriate for either committee to share their minutes directly with PIs. The NIH Guidelines require the dissemination of IBC meeting minutes to the public upon request and that a PI could be considered a member of the public. The IBC concurred that requests of minutes and other confidential IBC information would be considered on a per case basis. It was further noted that Dr. J. Mulshine, the new Associate Provost for Research, should address the interplay and sharing of information between the Institution's regulatory committees including the IRBs, IBC, and IACUC.

IBC Application. The current, revised version of the IBC application is not yet posted on the Associate Vice President for Research website. Drs. W. Knudson and J. Oswald and D. Haywood would look into this and assure that the appropriate version of the application form is posted.

12. Meeting adjourned at 12:14 pm: Motion: Dr. J. Oswald; Second: Dr. J. Bremer; Vote: For: 10;
Against: 0;
Abstentions: 0

Minutes submitted by: J. Oswald, D.V.M.

Meeting Minutes January 26, 2006**Present:**

E. Sondergaard
 T. Green
 W. Knudson, Ph.D.
 J. Oswald, D.V.M
 S-P. Kwan, Ph.D.
 A. Tenorio, M.D.
 N. Lurain, Ph.D.

Absent:

L. Brodsky, M.P.H.
 L. Valentino, M.D
 S. Pur, R.N., B.S.N
 J. Bremer, Ph.D.
 M. Bowman, Ph.D.

The meeting was called to order at 11:15 am

The minutes for the July 28, 2005, IBC meeting were approved.: Motion: Dr. J. Oswald; Second: Drs. N. Lurain & A. Tenorio; Vote: For: 7; Against: 0; Abstention: 0

The IBC concurred with the applications receiving expedited review and approval since July 28, 2005:

Investigator	ORA#	TITLE
Y. Murad	05081909	In Vitro and In Vivo Characterization of Link Protein-3 (LP3)
C. Forsyth	04092803	Metalloprotease-EGFR Regulation of Intestinal Barrier
L. Thomas	04122804	Neutrophils and HIV-1 Infection
A. Jaramillo	05081103	Characterization of the Cytotoxic CDB+ T Cell Immune Response to Mammaglobin-A

The IBC concurred with the applications receiving annual renewal since July 28, 2005:

Investigator	ORA #	TITLE
G. Schaer	04021003	A Multi-center Randomized Double Blind Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered via [Company Name] Stiletto Endocardial Injection Catheter pVGI.1 (VEGF2) (Placebo, 20, 200, or 800 µg) In Patients with Class III or IV Angina with an Option for Patients to Receive Active Treatment at One Year If They Experience a Treatment Failure

Old Business

Dr. J. Mulshine had invited a consultant group to meet with various members of Rush research administration including Drs. W. Knudson and J. Oswald and the Occupational Safety group to evaluate various aspects of the IBC, including the need for an Institutional Biosafety Officer (BSO). A draft of the consultants' report should be available by the week of February 6, 2006 and this report will be relayed to the IBC.

New Business

Dr. W. Knudson announced that he will be leaving Rush as of March 1, 2006 and that Dr. J. Mulshine will be appointing an interim chairperson to the IBC until the consultants' report is received and evaluated. There was some discussion regarding the selection of the interim IBC chairperson. It was also noted that the IBC administrative coordinator had left Rush and that D. Haywood would administer the IBC until the vacant position is filled.

- IBC members discussed general IBC membership and participation. It was noted that many faculty members are leaving Rush, that faculty participation on regulatory committees is becoming onerous, and that Dr. J. Mulshine should be made aware of these concerns.

(Dr. A. Tenorio arrived at the meeting.)

- It was the consensus of the IBC that when new IBC members are appointed, they should receive training information from the chairperson and the CRC administrative staff.
- Ms. D. Haywood will send and receive IBC application reviewer comment sheets via electronic mail to facilitate the review process. IBC members discussed the current 2-week deadline of IBC submissions prior to review at the next meeting. The deadline may be extended to 3 weeks if the reviewing task becomes too onerous.

Adjournment: Meeting adjourned at 11:52 am: Motion: Dr. J. Oswald; Second: Dr. W. Knudson; Vote: For: 7; Against: 0; Abstention: 0

Minutes submitted by: J. Oswald, D.V.M.

Meeting Minutes September 28, 2006**Present:**

J. Bremer, Ph.D.
 S. Pur, R.N., B.S.N.
 M. Bowman, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M
 A. Tenorio, M.D.
 L. Brodsky, M.P.H.
 T. Green
 E. Sondergaard
 A. Virdi, Ph.D.
 E. Blazek, Ph.D.

Absent:

L. Valentino, M.D.

The meeting was called to order at 11:10am. The minutes from the January 26, 2006 IBC meeting were approved. Motion: Dr. J. Oswald; Second: Dr. N. Lurain; Vote: For: 6; Against: 0; Abstention: 2

The IBC concurred with the applications receiving expedited review and approval since January 26, 2006:

Investigator	ORA#	TITLE

The IBC concurred with the applications receiving approval after PI made changes requested by the IBC since January 26, 2006:

Investigator	ORA #	TITLE
A. Aroutcheva, Ph.D.	06021515	Natural antimicrobials against bacterial vaginosis
X. Xu, Ph.D.	05100301	Pathogenic role of heparanase in pancreatic cancer-mediated proteinuria
X. Xu, Ph.D.	05111601	Uric Acid Crystals as a novel Adjuvant for HER-2/neu-based Immunotherapy in a Somatic Mammary Carcinoma Model
J. Kordower, Ph.D.	05072801	Gene Therapy in a Genetic Nonhuman Primate Model of Huntington's Disease
R. Sumner, Ph.D.	06050302	Adenovirus based gene transfer for bone implant fixation
X. Xu, Ph.D.	06080102	Role of heparanase-1(HPR1) in breast tumor angiogenesis growth
G. Spear, Ph.D.*	06080205	Evolutionary Lead Optimization for Immunotherapy of Marburg and Ebola Viruses

*It was noted that the Spear proposal above involves the transfer of genes for viral capsid proteins into a defective vector for a cell culture system. Complete infectious virus particles cannot be generated.

The IBC concurred with the new IBC Applications since January 26, 2006:

Investigator	ORA #	TITLE
K. Pahan	06082105	Statin and phenyl acetate in MPTP mouse model [Protocol No.]

The Committee's previous concern that a treatment protocol be established for any individual inadvertently exposed to MPTP has been satisfactorily addressed by the PI and his department.

The IBC concurred with the applications receiving annual renewal since January 26, 2006:

Investigator	ORA #	TITLE
F. Cohen	82051941	A Model System for Physiological Exocytosis
G. Spear	03052002	Activation of Innate Immunity by Filovirus Glycoproteins
J. Bremer	05050601	Generation of Standards for Use with Molecular Assays
G. Andersson	01060401	Intervertebral Disc Degeneration and Regeneration
L. Verhagen	05033101	A Phase I, Open-Label Study of [Agent Trade Name] Adeno-Associated Virus Serotype 2 (AAV2)- Neuturin (NTN) to Assess the Safety and Tolerability of Intrastriatal Delivery to Subject with Idiopathic Parkinson's Disease [Protocol No.]
G. Schaer	04021003	A Multicenter, Randomized, Double-blind, Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered via [Company Name] Stiletto™ Endocardial Injection Catheter pVGL1(VEGF2) (placebo, 20, 200, or 800 mg) In Patients With Class III or IV Angina

1. Old Business: None.
2. New Business:

(Dr. A. Tenorio and Ms. S. Pur arrived at the meeting.)

An administrative error was made whereby the principal investigator of a particular IBC application was inadvertently made aware of the IBC member reviewers of the application. This was disconcerting to the reviewers. This error was recognized and steps have been taken to assure that this error does not recur.

There was a discussion about the present IBC application distribution and review process. The IBC concurred that new applications will continue to be directed to the IBC chairperson, who will assign review of the application to the Biological Safety Officer (BSO), whose appointment is imminent, and to IBC member scientists. The comments and recommendations of these individuals will be included on the agenda for the next IBC meeting (currently scheduled for November 30) for discussion of all applications submitted from today until November 23. The IBC concurred that the process should be re-evaluated and discussed at the next convened meeting.

Dr. A. Viridi was introduced as the new IBC Chairperson.

3. Adjournment: Motion: Dr. J. Bremer; Second: Dr. J. Oswald; Vote: For: 10; Against: 0; Abstention: 0.
Minutes submitted by: J. Oswald, D.V.M.

Rush University Medical Center--Institutional Biosafety Committee Minutes

This document contains all approved minutes of IBC meetings after 1 May 2003 to 6 November 2006.

Company names, external protocol numbers, and agent trade names of investigational agents have been visibly redacted to protect proprietary commercial interests, consistent with the NIH OBA (Patterson) memo of 5/14/04. These redactions are identified as to type: [Company Name], [Protocol No.], [Agent Trade Name].

Abbreviations used in Minutes:

AAV	adeno-associated virus
BBPT	Bloodborne Pathogen Training
BSL1	Biosafety Level 1
BSO	Biological Safety Officer
cAMP	3'-5'-cyclic adenosine monophosphate
CDC	Centers for Disease Control
CRC	(Rush) Comparative Research Center
DA	dopaminergic (neurons)
EGFR	epidermal growth factor receptor
FDA	Food and Drug Administration
GDNF	glial cell-derived neurotrophic factor
GTP	guanosine-5'-triphosphate
HGF	hepatocyte growth factor = hepapoietin A
HIF1 α	hypoxia-inducible factor 1 alpha
HIV	human immunodeficiency virus
HPR1	heparanase-1
HSV	Herpes simplex virus
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IL-13	Interleukin-13 (as protein not DNA)
IRB	Institutional Review Board
MPTP	1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine
NGF	nerve growth factor
OBA	Office of Biotechnology Activities
ORA	(Rush) Office of Research Affairs
RAC	(Federal) Recombinant DNA Advisory Committee
rDNA	recombinant DNA
VEGF	vascular endothelial growth factor

Meeting Minutes May 15, 2003

Present: J. Bremer, Ph.D.
L. Brodsky, M.P.H.
T. Green
W. Knudson, Ph.D.
J. Kordower, Ph.D.
S-P. Kwan, Ph.D.
J. Oswald, D.V.M.
M. Peeples, Ph.D.
S. Pur, R.N., B.S.N.
D. Simon, M.D.

Absent: D. Clark, Ph.D., *ex officio*
P. Cronce, Ph.D.

Meeting called to order at 11:15 a.m.

1. New committee member introduced: E. Sondergaard
2. Approval of minutes from March 20, 2003 meeting: MOTION to approve, seconded, motion passed.
3. Expedited approvals since March 20, 2003:

Investigator	ORA#	TITLE
J. Bremer	98111701	Virology Quality Assessment Program
M. Peeples	02052301	Translation Regulation in Sendai Virus

4. Approved after PI made changes requested by the IBC:

Investigator	ORA #	TITLE
J. Kordower	03042204	Neurturin Gene Therapy in a Rat Model of Huntington's Disease
J. Qiao	03010303	Regulation of Rho GTPases by cAMP-dependent Protein Kinase: Protective Mechanism Against Endothelial Barrier Dysfunction

D. Simon entered the room

5. A "Code Orange" plan for internal preparedness plan is being developed. This plan will be discussed at the next meeting.
6. The Center for Disease Control Select Agents list was presented. This list has been added to the end of the IBC application form.

S. Pur entered the room

7. Select agents and toxins destruction form: need to add a line for quantities. Rush investigators previously registered with the CDC were removed from the registry according to these criteria:
 - (a) they are doing clinical work that does not need to be reported
 - (b) they possess less than a specified quantity of an agent or toxin
 - (c) they have destroyed or used up the agent or toxin

This information was provided to the CDC in writing.

Do the clinical laboratories need to report select agents and toxins? CDC guidelines require clinical labs to report possession of select agents and toxins, even if it is for diagnostic purposes only. Also, the CDC requires that the agent or toxin be destroyed within a certain period of time. If it is being stored for longer than the given period, the CDC must be assured that it will be stored in a locked and secure facility, and that the staff has Department of Justice security clearance to handle these materials. Dr. M. Hayden has a clinical lab and, therefore, should be notified of the notification/reporting regulations set forth by the CDC. Are there special methods for destruction? Each material is unique and must be identified and destroyed appropriately.

8. New/Tabled IBC Applications

Investigator	ORA #	TITLE	
J. Snell	pending	Protocol [Protocol No.]: A phase II multi-center, double-blinded, placebo-controlled trial of [Agent Trade Name] in intermittent claudication secondary to peripheral arterial disease	
C. Sortwell	01071203	Angiogenic Enhancement of Dopamine Neuron Grafts	
W. Knudson	95101801	CD44-Mediated Catabolism of Hyaluronan by Chondrocytes	

W. Knudson Study Discussion:

The procedure for the study was described. Lentivirus delivered from the company cannot propagate. Everything seems to be addressed correctly on the application. The Lab Rules attached need to be investigator's own. For question #13 insert "Fill out employee health injury form." (Employee Health requires a form before seeing the employee.) Soap and water for needle sticks are better than 70% alcohol.

W. Knudson left the room

MOTION: Conditional approval pending changes was moved, seconded, and passed.

N.B. The recommended changes were made and final approval was granted on May 19, 2003

W. Knudson entered the room

J. Snell Study Discussion:

This is a Phase II, human study. Plasmid suppresses angiogenic factors in those with Peripheral Arterial Disease. Phase I has already been done. The product was tolerated well; only local bruising at site of injection was noted. Phase I study continues for long-term toxicity. The concern is that prior subject screening may miss a cancer, and this product may enhance tumor growth. The Office of Biotechnology and RAC had no comments. The study is appropriately categorized as BSL1. Bloodborne pathogen training needs to be updated for three people involved in the study. Little systemic distribution of the study agent has been observed in animals. Its efficacy in human studies is not known. The consent form is appropriate. This seems to be a reasonable study from an IBC standpoint. Study requires 22-28 injections—staff needs to wear eye protection and gloves. Appendix M needs to be updated for Rush—site-specific information required (M2b5a-M2b5b). In case of accidental needle sticks or exposure, there is a possibility of spreading. The PI is asked to make the following changes:

- Changes site-specific answers in Appendix M
- Wear eye protection and gloves when giving injections
- Update BBPT dates
- Improve statement of procedures for accidental needle sticks
- Question #12: recommend 10% bleach concentration or Virex 256

- Question #13: wash with soap and water, then fill out accident report and go to Employee Health Services

MOTION: Conditionally approved pending recommended changes, seconded, and passed. Recommended changes were submitted, and final approval was granted on May 27, 2003

C. Sortwell Study Discussion:

Rush IACUC has already approved this study. This group studies Parkinson's disease. The therapeutic principle is that cellular grafts could help overcome the disease. In this study, they are adding a component to increase vascularization, hoping it will prolong viability of the graft. Biosafety Category IIID1 is appropriate. Initial transfection may end up with some HSV (10^{-6} probability). C. Sortwell will be the only person handling the vector—her BBPT needs to be updated (last renewal 7/2002). Of the others listed on the grant application, who would need BBPT? HSV does not infect rats; it will not be transmitted through the experimental host animal. It is only a concern for those doing the initial injection. PI needs to include/change:

- Question #11: disposal by Stericycle. The Tech 2000 facility has separate contract for waste disposal; thus, Rush Biohazard is NOT responsible.

T. Green will review and clarify waste disposal section. Ultimately, the PI is responsible for proper waste disposal. Do the people who are handling HSV prior to the injection require BBPT? No, by the time the staff is preparing to inject, the HSV is already gone. Environmental services does not service Tech 2000—remove from question #12 and the safety sheet.

- For waste disposal, autoclaving is not necessary—red Biohazard bag disposal is okay.
- Occupational Safety also needs to be removed from the application.
- In case of exposure, employee needs to fill out form and report in person to Employee Health Services, not just call them.

MOTION: Approve by Chairperson pending changes: moved, seconded, and passed. Recommended changes were submitted, and final approval was granted on January 5, 2004.

9. Do routine vector studies require full committee review or expedited review? These decisions were reached by the IBC.
 - Routine work with infectious agents—expedited.
 - Human or animal studies—full committee review.
 - Cell cultures, defective vectors, etc.—expedited.
 - Anything new—Chairperson can send to committee if necessary.
 - Virus vectors—Chairperson's decision to send to full committee or expedite.
 - Defective virus vectors *in vitro*, and adenovirus—Chairperson's decision to send to full committee, expedite, or consult with committee members and/or experts.
 - Routine defective virus vector genes—expedited.

We should actively promote IBC awareness.

MOTION: Approve procedures as stated: moved, seconded, and passed.

Meeting adjourned at 12:15pm. Minutes submitted by G. Ahuja.

Meeting Minutes January 22, 2004**Present:**

E. Sondergaard
 L. Brodsky, M.P.H.
 T. Green
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M.
 M. Peeples, Ph.D.

Absent:

D. Clark, Ph.D., *ex officio*
 P. Cronic, Ph.D.
 J. Bremer, Ph.D.
 S. Pur, R.N., B.S.N.
 A. Tenorio, M.D.

Meeting called to order at 11:10 a.m.

1. New committee members: N. Lurain, Ph.D. and A. Tenorio, M.D. Introduced: N. Lurain.
2. Updated NIH Guidelines distributed.
3. Approval of minutes from May 15, 2003 meeting: **MOTION: approve, seconded, motion approved**
4. Expedited Since May 15, 2003

Investigator	ORA#	TITLE
M. Emborg	02072206	Lentiviral Delivery of GDNF-TET to aged Nonhuman Primates
M. Emborg	03031902	Lentiviral Delivery of GDNF 3 Months Post MPTP Treatment
R. Loeser	03092505	Dysregulation of the Chondrocyte in Aging Cartilage
G. Spear	03052002	Activation of Innate Immunity by Filovirus Glycoproteins
G. Spear	03010201	Cell Surface Interactions Important for HIV Infection
T. Glant	04011903	Mouse Link Proteins: Expression and Function
W. Knudson	04011904	Hyaluronan Fragment Signaling and Cartilage Degeneration

5. Approved after PI made changes requested by the IBC

Investigator	ORA #	TITLE
W. Knudson	95101801 Amendment	CD-44 Mediated Catabolism of Hyaluronan by Chondrocytes
J. Snell	03050502	[Protocol No.]: A phase II multi-center, double-blind, placebo-controlled, trial of [Agent Trade Name] in subjects with intermittent claudication secondary to peripheral arterial disease
C. Sortwell	01071203	Angiogenic Enhancement of Dopaminergic Neuron Grafts

6. Do animal studies need to go to full committee review? Only those animals being injected with rDNA require full-committee review. Transfection into eukaryotic cells may be expedited by the chairperson. Revise May 2003 minutes to clarify these points. The ORA Proposal Routing Form should include a checkbox for "IBC Exempt".
7. Is it convenient for everyone if we move the meetings to the fourth Thursdays instead of the third Thursdays? Decide later via email poll.

8. Amendment Form: Amendments require detailed explanations of waste disposal, needle-sticks, etc. A short version of the original form may not be sufficient. PI should be required to use the original application with a checkbox for “amendments”. Application should be appended to include policy numbers. Policy numbers will be added with the help of T. Green. **MOTION: revise original application so that it can be used to submit amendments, seconded, and passed.**
9. Announcing new chairperson: W. Knudson, Ph.D. Who should be the co-chair? Co-chair will be assigned at a later date.
10. Internal Response Plan introduced by T. Green will be discussed at the next meeting.

W. Knudson left the room

11. Select Agents and Toxins Destruction form has been revised to include a line for quantities as stated in the May 2003 minutes.

12. New/Tabled IBC Applications

Investigator	ORA #	TITLE	
C. Sortwell	03052703	Evaluation of Hypoxia in Grafted DA Neurons	

Discussion: Is investigator using virus vectors? Yes, but it is not infectious to animals. *In vitro*, it can be infectious for a single cycle, but no infectious agent is being injected into the animals.

Ask PI to make the following changes:

- Question #11 - check off “Rush Biohazard Removal” for any additional solid waste.
- Question #13 – Hamilton syringe is okay, but are any other syringes being used? If so, describe precautions being taken, and needle-stick procedures to be followed.

MOTION: chairperson shall approve pending changes, seconded, and passed.

Meeting adjourned at 12:20pm. Minutes submitted by: G. Ahuja, MPH

Meeting Minutes March 25, 2004**Present:**

T. Green
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M
 E. Sondergaard
 A. Tenorio, M.D.

Absent:

L. Brodsky, M.P.H.
 D. Clark, Ph.D., ex officio
 P. Cronce, Ph.D.
 J. Bremer, Ph.D.
 S. Pur, R.N., B.S.N.

Meeting called to order at 11:09 a.m.

1. Introduction of T. Hale (G. Ahuja's replacement).
2. Approval of minutes from January 22, 2004 meeting: **MOTION: moved, seconded, and passed.**
3. Expedited Since January 22, 2004

Investigator	ORA#	TITLE
NONE		

4. Approved after PI made changes requested by the IBC

NONE		

5. New/Tabled IBC Applications

Investigator	ORA #	TITLE
Z. Arvanitakis	04032903	A Phase I, Dose-Escalating Study to Assess the Safety and Tolerability of [Agent Trade Name] Adeno-Associated Virus (AAV)-based, Vector-Mediated Delivery of Beta Nerve Growth Factor (NGF) in Subjects with Mild to Moderate Alzheimer's Disease. [Protocol No.]
G. Schaer	00021004	A Multi Center, Randomized, Double-Blind, Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered Via [Company Name] Stiletto Endocardial Injection Catheter pVGI.1 (VEGF2) (placebo, 20, 200, or 800 µg) In Patients With Class III or IV Angina With An Option For Patients To Receive Active Treatment At One Year If They Experience A Treatment Failure

6. Member stated that there is no other potential danger besides the normal risk that the adeno-associated virus would cause in the Z. Arvanitakis study.
7. Member noted that the NIH already approved this study, and recommends approval provided that investigator changes intervals from once every month to once every 3 months as RAC had requested, and provided blood borne pathogen training of staff is completed.

A. Tenorio entered the room at 11:30am

8. Member poses question about operational policies used on page 11, stating that it should be changed to Operational Policy 203, 147, and 277. Member also states that on page 12 (item 13), the Operational Policy should be changed to 191.
9. Member moves to approve this study pending: Blood Borne Pathogen training, new changes in operational policies, and RAC request amended in Rush's file for this study. Motion is seconded, no discussion, motion carried.

Introductions are done again since Dr. A. Tenorio has arrived.

10. Second study discussed, G. Schaer. Member had questions about changes in protocol (i.e., lab location and microorganisms used).
11. Member asks whether the IBC should ask for consent forms.
12. Member asks "Do we (IBC) consistently ask for IRB forms for all studies"?
13. Member states that previously IRB consents were not required.
14. Member states that on page 9 item #11 the item needs to be destroyed before they remove it. Autoclaving would be sufficient.
 - a. Member moved that we approve this study pending revisions to Biohazards and RAC amendment letter, motion seconded, no discussion, motion carried.
 - b. Member asks "is there a co-chair"?
15. Member suggests Dr. J. Bremer as co-chair.
16. Member points out that Dr. J. Bremer is sometimes absent and that co-chair needs to be there when chair is not.
17. Member wants to know if we need a named co-chair, or can we have an *ad hoc* co-chair chosen from among attendees?
18. Decided that there will be an *ad hoc* and Dr. W. Knudson will appoint people as needed.
19. Should we (IBC) make copies of applications, or should the PI?
20. Member states PI should be responsible for copies; that is consensus of members.
21. Member: IBC shouldn't review an application unless copies are attached.
22. Member suggests sending out a broadcast email introducing new members and # of application copies to be submitted.

Meeting adjourned at 12:01pm. Minutes submitted by T. Hale.

Meeting Minutes May 27, 2004**Present:**

J. Bremer, Ph.D.
 P. Cronic, Ph.D.
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M.
 A. Tenorio, M.D.

Absent:

L. Brodsky, M.P.H.
 D. Clark, Ph.D., ex officio
 E. Sondergaard
 S. Pur, R.N., B.S.N.
 T. Green

Meeting called to order at 11:10 a.m.

1. Approval of minutes from March 25, 2004 meeting. **Motion: moved, seconded, motion approved**
2. Expedited Since March 25, 2004

Investigator	ORA#	TITLE
L. Valentino	04011604	Induction of Hemophilic Synovitis in Mice Deficient in Osteopontin
L. Valentino	Not Assigned	Factor IX Replacement Therapy to Prevent Hemophilic Synovitis in Factor IX Deficient Mice

3. Approved after PI made changes requested by the IBC

Investigator	ORA#	TITLE
Z. Arvanitakis	04032903	A Phase I, Dose-Escalating Study to Assess the Safety and Tolerability of [Agent Trade Name] Adeno-Associated Virus (AAV)-based vector- Mediated Delivery of Beta Nerve Growth Factor (NGF) in Subjects with Mild to Moderate Alzheimer's Disease. [Protocol No.]
G. Schaer	00021004	A Multicenter, Randomized, Double-Blind, Dose Ranging Placebo Controlled Study Evaluating Defined Doses of Percutaneously Delivered Via [Company Name] Stiletto Endocardial Injection Catheter Pvg.1 (VEGF2) (placebo, 20, 200, or 800ug) In Patients With Class III or IV Angina With An Option for Patients To Receive Active Treatment At One Year If They Experience A Treatment Failure

4. New/Tabled IBC Applications

Investigator	ORA #	TITLE
R. Byrne	04040803	A Phase III Randomized Evaluation of Convection Enhanced Delivery of [Agent Trade Name] Compared to Gliadel Wafer with Survival Endpoint in Glioblastoma Multiforme Patients at First Recurrence [Trial Name, Protocol No.]
G. Spear	04031901	A Murine Model of HIV Genital Tract Infection

Discussion

5. Committee discusses if this study will even need IBC approval because everything was being handled at the company [Company Name]. IL13 is a protein, rather than a recombinant DNA, which removes the possibility of genetic transmission. All protocols seemed to be very "clean."

6. A proposal is made that a letter be written to the IRB stating that the study does not need IBC approval, and to thank the IRB for the opportunity to review the study. The IBC will welcome all future reviews when the IRB is in doubt about whether a study needs IBC approval.
7. It is agreed that the research staff of this study needs Blood Borne Pathogen Training.

Discussion of G. Spear Study:

Committee discusses whether Dr. G. Spear turned in revised form. It is decided that Dr. G. Spear will need to go to the website and get the online version of the recently updated IBC rules hand book.

J. Bremer entered the room at 11:25am

A member of the committee asks if Section IIID box D3 applies to this study. The IBC decided that Section IIID box D4 should be checked off. Another member asks if the study should be tabled?

8. Committee decides against tabling the application. They will grant it provisional approval, provided that the Principal Investigator submits revisions that were requested: Check appropriate box in application form, complete entire application.
9. Motion for provisional approval made: committee member asks “what is the endpoint Dr. G. Spear is looking for?” Another member replies that investigator wants to see if mice will become infected.
10. Previous motion for provision approval: seconded and passed.

Discussion of J. Zhang Study:

1. This study was previously approved under Dr. M. Peeples’ chairmanship. Committee chair recommends administrative approval since Dr. J. Zhang is just resubmitting it for grant approval.
2. Community member expresses concern that project description is written in very scientific language and needs to be simplified.
3. Chairman agrees to address this when he gives administrative approval.
4. Committee notes that their Blood Borne Pathogen Training has expired and their Biohazard Hood certification is overdue.
5. Motion for conditional approval pending update of Blood Borne Pathogen and Biohazard Hood re-certification was seconded and passed.
6. The chairman of the committee asks Dr. J. Bremer whether there is a reason for the submission of 12 copies of the IBC application, but not its supplemental information?
7. Committee discusses the possibility of there being a submission of 12 copies of the supplemental information and not just 2. Committee decides not to decide on it today.
8. There is discussion on the operational procedures being revised and also the route to access the IBC applications on line.
9. Member has further concerns about the R. Byrne study and would like to review it more before writing the letter saying that it will not need IBC approval. The question of concern is whether toxins fall under the jurisdiction of the Institutional Biosafety Committee.
10. The date of the November meeting needs to be changed due to the holiday.
11. Committee agrees to meet the Thursday before Thanksgiving.

Meeting adjourned at 12:40 pm. Minutes submitted by T. Hale, B.S.

Meeting Minutes October 21, 2004**Present:**

J. Bremer, Ph.D.
 L. Brodsky, M.P.H.
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 E. Sondergaard
 A. Tenorio, M.D.

Absent:

D. Clark, Ph.D. ex officio
 P. Cronce, Ph.D.
 T. Green
 J. Oswald, D.V.M.
 S. Pur, R.N., B.S.N.

Meeting called to order at 12:07 p.m.

Approval of minutes from May 27, 2004 meeting. **Motion for provisional approval pending the correction of Dr. J. Bremer's last name and E. Sondergaard and T. Green being absent: moved, seconded, and passed. 5 yes, 0 no.**

Chairman would like to know if committee member S. Pur is still a part of the committee or would she like to offer someone else from her department to take her place on the committee.

1. Expedited Since May 27, 2004

Investigator	ORA#	TITLE
T. Glant	89050101	Auto Immune Progressive PolyArthritis
B. Cole	04090201	Tissue Engineered Human Neocartilage to Repair Goat Full Thickness Cartilage
T. Collier		The Trophic Factor Pleiotrophin: Neuroprotection and graft-derived reconstruction of the nigrostriatal system
Y. Zhang		Gene Therapy for Intervertebral Disc Degeneration
F. Huang		Lysophosphatidylcholine promotes monocyte transmigration by a novel specific G protein-coupled receptor expressed by endothelial cells
G. Schaer	0021004	A Multicenter, Randomized, Double-Blind, Dose Ranging Placebo Controlled Study Evaluating Defined Doses of Percutaneously Delivered Via [Company Name] Stiletto Endocardial Injection Catheter Pvg.1 (VEGF2) (placebo, 20, 200, or 800ug) In Patients With Class III or IV Angina With An Option for Patients To Receive Active Treatment At One Year If They Experience A Treatment Failure

Discussion: Chairman explains that all of the expedited studies that gained approval involved all drugs that were commercially available.

2. Approved after PI made changes requested by the IBC

Investigator	ORA#	TITLE
J. Zhang*	00061205	Cbl-b in cell activation and autoimmunity
G. Spear	04031901	A Murine Model of HIV Genital Tract Infection
L. Valentino*	01012604	Proto-oncogene expression in hemophilic synovitis

*Consistent with established IBC procedures for low-risk protocols, the changes were requested by the IBC chair as the representative of the committee.

3. New/Tabled IBC Applications

Investigator	ORA #	TITLE
R. Byrne	04040803	A Phase III Randomized Evaluation of Convection Enhanced Delivery of [Agent Trade Name] Compared to Gliadel Wafer with Survival endpoint in Glioblastoma Multiforme Patients at First Recurrence [Trial Name, Protocol No.]
J. Snell	Not assigned	A Phase II Double-Blind, Randomized, Placebo-Controlled Study To Assess The Safety And Efficacy Of [Agent Trade Name] to Improve Perfusion In Critical Leg Ischemia

Discussion of R. Byrne Study:

4. Chairman discusses and passes out a copy of the letter that he sent to the IRB regarding the decision that Dr. R. Byrne's study did not need to receive IBC approval
5. Committee agrees that the letter is appropriate and would like to know if the study eventually gained IRB approval. IBC coordinator informs the committee that the study did receive IRB approval.
6. Member reiterates his concern that the *E. coli* may multiply and produce toxins.
7. The chairman discusses his conversation with Dr. D. Clark about the concerns that the committee had and informed the committee that he and Dr. D. Clark discussed the option of forming another committee that would look at studies with drugs that are not FDA-approved.
8. The chairman addresses the issue that the IBC will continue to review all studies to make the determination whether it needs IBC approval or not.
9. Chairman states if there are no studies to go to full committee on next month, the November 21st 2004 meeting will be cancelled.

J. Snell Study:

Description of study: The description of study was given by the primary reviewer. This is a study of the [Agent Trade Name] gene transfer product commonly known as "HGF Plasmid". It is sponsored by [Company Name]. The product is distributed to 25 sites and only 4 subjects are enrolled here at Rush; hence Rush plays a small part in this large-scale study.

Discussion: A committee member questions whether routine Rush Biohazard disposal is sufficient? The consensus is that their biohazard disposal method is suitable. It is good practice to destroy biological activity before putting it on public roads. Since the transfer method is syringe, putting them into the proper biohazard waste container is fine.

2. Member asks if the lab rules are sufficiently detailed to approve. Chairman explains that lab rules were modified explicitly for this study, and that in chair's judgment, they are okay.
3. Member would like to know if Appendix M has been modified to explain this particular study at Rush or are they using a general Appendix M for all the sites of this study.
4. Reviewer of this study explains she did not see anything wrong or unusual with this study's appendix M, and it was tailored to Rush's specific site.
5. Member would like to know if there is an informed consent. There is an informed consent document, but the IBC does not require it to be submitted for review.

6. The primary reviewer's comments are as follows: "PI needs to update Blood Borne Pathogen training and degradation agent such as UV light needs to be used to inactivate DNA".

7. Chairman gives the comments of the second reviewer's revisions, because this reviewer has not yet arrived to the meeting. "Section 8C should describe E. coli strain not plasmid, and section 12 should use DNA degradation agent such as UV light or DNA lamp".

There is a motion made to provisionally approve the study pending revisions, and any further comments from secondary reviewer. Motion seconded and passed: 5 yes, 0 no, 0 abstentions

N. Lurain entered the room at 12:39 p.m.

1. Committee informs N. Lurain of the provisional approval of Dr. J. Snell's study and hands N. Lurain the letter that the chairman wrote to the IRB concerning Dr. R. Byrne's study.

2. Chairman discusses Dr. J. Kordower study that received provisional approval through expedited review, and brings to light the issue that the IBC does not have an official amendment form. That the current procedure is for the investigator to send a letter of the changes they would like to make.

3. Committee discusses new way to submit amendments to IBC applications.

A. A. Tenorio entered the room at 12:44 p.m.

4. Committee member suggests that to submit an amendment to a study, one should also submit the original approved application, an amendment letter describing the changes, and a new copy of the application form with the changes updated. If the experimental protocol itself is changed, a new protocol should be submitted. **Motion is made for the above suggestion; seconded, and passed. 7 yes, 0 no, 0 abstentions**

New Business:

1. The committee discusses the fact that there is no co-chair for the IBC committee and in the case that Dr. W. Knudson is not around to sign off on approval letters there needs to be a co-chair assigned to the committee or a designated committee member authorized to sign authorization letters.

2. Committee discusses and decides to let the primary and secondary reviewer be authorized to sign an IBC authorization letter if the chairman is not available.

Meeting adjourned at 12:59 pm. Minutes submitted by: T. Hale, B.S.

Meeting Minutes March 24, 2005

Present:

J. Bremer, Ph.D.
T. Green
W. Knudson, Ph.D.
S-P. Kwan, Ph.D.
N. Lurain, Ph.D.
J. Oswald, D.V.M.
E. Sondergaard
A. Tenorio, M.D.

Absent:

D. Clark, Ph.D. (*ex. officio*)
L. Brodsky, M.P.H.
S. Pur, R.N., B.S.N.

1. The meeting was called to order at 11:08 am. Introductions were made with a brief explanation of what each individual's role is on the IBC as well as within the institution.
2. The minutes from the October 21, 2004 meeting were approved: Motion: J. Oswald; Seconded: T. Green
Vote: For: 6; Against: 0; Abstain: 0
3. The members concurred with the expedited approvals since October 21, 2004:

Investigator	ORA#	TITLE
G. Maki	03111107	Evaluation of NK cells as a means of immunotherapy for hematological malignancies
W. Knudson	04011904	Hyaluronan Signaling and Cartilage Degeneration

4. There were no applications that were approved after PI made changes requested by IBC.
5. There were no new/abled IBC applications.
6. Old Business:
 - A. The IBC discussed whether there were any necessary changes to the existing IBC application or annual review forms. It was noted that V. Berry will send annual renewal notices to PI's beginning April 1, 2005.
 - B. The IBC discussed the type of applications within IBC jurisdiction. The IBC concurred that we may need to institute a specific submission form for use/handling of human tissue of unknown infectious status. Member stated that he will converse with Dr. D. Clark about this issue.
 - C. The IBC concurred that an ORA number must be assigned to an IBC application before it is considered by the Committee. Member stated that he is certain that an ORA number will be assigned to an application before it is received by V. Berry and forwarded to any IBC member.
 - D. The IBC concurred that only the local generation of transgenic animals requires an IBC submission, not simply the purchase and/or use of such animals generated elsewhere.
 - E. The IBC concurred that PI's should submit 2 copies of an IBC application for preliminary review. It was stated that if additional copies are required, V. Berry will contact the PI and make this request.
 - F. It was noted that the selection of the appropriate box on the application in question 4 is difficult for PI's to assess and complete. The IBC concurred that a PI completing the application must consult the NIH guidelines / website when completing the application. In addition, member stated that he will provide examples for investigators to assist in completing the application.

G. The IBC concurred that any IBC member can review applications to decide whether full committee review is warranted and may sign IBC correspondences, including approval letters, in Dr. W. Knudson's absence.

H. The IBC concurred that Drs. W. Knudson and J. Oswald should generate appointment letters for IBC members and develop a 2-year rotation for IBC membership.

7. New business:

A. The resignation of Dr. P. Cronic was discussed. Member stated that he would inquire as to whether any of the IACUC community members would consider IBC membership and that he would discuss a pipeline for community IBC members with Dr. D. Clark.

B. The issue of V. Berry providing administrative support to the IBC was discussed.

8. Meeting adjourned at 11:55 am: Motion: Dr. J. Oswald; seconded: Mr. T. Green
Vote: For: 8; Against: 0; Abstain: 0

Minutes submitted by V. Berry.

Meeting Minutes May 26, 2005**Present:**

M. Bowman, Ph.D.
 L. Brodsky, M.P.H.
 D. Clark, Ph.D. (*ex. officio*)
 T. Green
 W. Knudson, Ph.D.
 S-P. Kwan, Ph.D.
 J. Oswald, D.V.M.
 E. Sondergaard

Absent:

J. Bremer, Ph.D.
 N. Lurain, Ph.D.
 S. Pur, R.N., B.S.N.
 A. Tenorio, M.D.

The meeting was called to order at 11:15 am

1. Dr. W. Knudson opened the meeting by asking that everyone new to the IBC provide brief introductions. Dr. J. Oswald introduced M. Bowman, Ph.D. from the University of Illinois at Chicago.
2. The minutes for the March 24, 2005 IBC meeting were approved. Motion: Dr. J. Oswald; Seconded Dr. M. Bowman, and passed. Vote: For: 6; Against: 0; Abstain: 1
3. Dr. D. Clark was the next to speak. Dr. D. Clark began by explaining his role in attending the IBC meeting and future plans for the IBC's handling of applications in which only the handling of human tissues is conducted. The IBC concurred that with the assistance of Research Administration and Compliance, a Biosafety Officer (BSO) should be hired. The BSO would be responsible for assuring that Blood Borne Pathogen Training and training in the disposal of these materials is complete and appropriate. The responsibilities of the BSO would also included conducting inspections of and monitoring activities in the laboratories. Dr. D. Clark also explained that there will be a new Associate Provost for Research, Dr. J. Mulshine who should address whether the handling of human tissues falls under the jurisdiction of the IBC. Dr. M. Bowman explained how UIC handles these types of applications.
4. **Expedited Review and Approval Since March 24, 2005**

Investigator	ORA#	TITLE
R. Bakay	02101004	Stem Cells in CNS Transplantation
M. Delcommenne	05042801	Recombinant Human Antibodies Targeting Heparan Sulfate Motifs Specific of Multiple Myeloma Cells- Investigation of their Anti-Myeloma Tumoricidal Effects.
E. Mufson	05032502	Transgenic Mouse Models of Alzheimer's Disease
J. Qiao	05010601	PKA-induced Phosphorylation of GDP Dissociation Inhibitor: Role in Endothelial Barrier Function Regulation
E. Rios	02011102	Skeletal Muscle Ca ²⁺ Release Control Inside the SR
G. Spear	04082003	Murine Model of STD-enhanced HIV Transmission
L. Valentino	05032503	Effect of Recombinant Factor VII Prophylaxis on Hemarthrosis

5. New/Tabled IBC Applications for Full Committee Review

Investigator	ORA#	TITLE
G. Schaer	05051102	A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center, Dose-selection of Ad2/Hypoxia Inducible Factor (HIF)-1 α /VPI6 in Patients with Intermittent Claudication-Walk Study [Protocol No.]
J. McAuley	05051002	Phase I open Label Study to Evaluate the Safety at Tolerability of recombinant HIV +.

Investigator	ORA#	TITLE
L. Verhagen	05033101	A Phase I, Open-Label Study of [Agent Trade Name] Adeno-Associated Virus Serotype 2 (AAV2)-Neurturin(NTN) to Assess the Safety and Tolerability of Intrastriatal Delivery to Subjects with Idiopathic Parkinson's Disease [Protocol No.]
J. Bremer	05050601	Generation of Standards for Use with Molecular Assays.

Discussion of ORA# 05051002 (J. McAuley Application)

Reviewer stated that this application describes a phase I clinical trial to determine the safety of recombinant DNA vaccines utilizing a modified Vaccinia virus and a modified fowl pox virus. He stated that the vaccines will express the “gag” and other proteins of the HIV virus in hopes of generating an antibody response to these viral proteins in sixteen HIV-positive, non-AIDS patient volunteers. A major question regarding this application was whether it required review by the federal Recombinant DNA Advisory Committee (RAC). After extensive discussion, the IBC concurred that this application is in fact exempt from RAC review. It was noted that the modified Vaccinia virus vaccine has been administered to over 100,000 human patients as a smallpox vaccine and there were a small number of adverse events in the trial in which this vaccine was administered. The IBC concurred that the PI of this application should be specific as to the personnel who will be administering the trial vaccines and to assure that these individuals will have the opportunity to be vaccinated against Vaccinia and that routine medical surveillance will be provided for these individuals. The IBC concurred that the disposal method and potential spill procedures for the trial vaccines should be more specific. In addition, the specific area in which these trial vaccines will be administered must be identified and post-vaccination clean-up procedures for this area must also be explained in the application. Lastly it was noted that there were several other errors in completing the application which must be corrected/clarified prior to approval of this application. After some additional discussion, a motion was made, seconded and passed to table this application until the PI has responded to the IBC's concerns and until the next regularly scheduled IBC meeting.

Motion to Table: Dr. W. Knudson; Second: Dr. J. Oswald; Vote: For: 6; Against: 0; Abstain: 1

Discussion of ORA# 05051102 (G. Schaer Application)

The primary reviewer of this application was absent from the meeting. The secondary reviewer stated that this application described the administration of a recombinant DNA, replication-defective adeno-associated viral vector clone inserted in a cell line to generate blood vessels in a group of 300 patient volunteers. It was stated that [Company Name] would like to test this therapy in four different doses. The secondary reviewer discussed her comments which included that the PI must provide a map of the construct. The IBC concurred that not all personnel to be involved in the project had completed up-to-date blood-borne pathogen training and that the containment level should have been indicated as BL2 but was labeled BL1. The IBC concurred that lab rules for the project must be provided. There were other criticisms, including that the IBC should inquire whether each lot of the final product is tested for recombination events *in vitro*. The IBC concurred

that the PI must also provide a copy of the initial consent document for patient volunteers enrolling in the trial as well as the specific RAC comments provided to [Company Name]. The IBC concurred that errors in the application occurred on pages 6, 7 and 8 and must be clarified/corrected. After some additional discussion a motion was made, seconded and passed to table this application until the PI has responded to the IBC's concerns and until the next regularly scheduled IBC meeting.

Motion to Table: Dr. J. Oswald; Second: Mr. T. Green; Vote: For: 7; Against: 0; Abstain: 0

Discussion of ORA# 05050601 (J. Bremer Application)

Reviewer provided a brief overview of the application and discussed the primary reviewer's comments. The IBC concurred that the PI must assure that the biosafety cabinet listed in item #6 on page 6 has been certified and that the PI must list HIV-1 as a human hazard in item #9A on page 7 of the application. In addition, the IBC concurred that the risk group classifications, III for HIV-1 and II for Sindbis virus, should be recorded in item #8D on page 7 of the application. Lastly, the IBC concurred that the answer to item #9B on page 7 should be changed from "not applicable" to "no" After some additional discussion, a motion was made, seconded and passed to approve this application pending the submission of the clarifications discussed above.

Provisional Approval Motion: Dr. J. Oswald; Second: Dr. M. Bowman; Vote: For: 7; Against: 0; Abstain: 0

Discussion of ORA# 05033101 (L. Verhagen Application)

Reviewer stated that this application described the administration of the neurturin (NTN) gene incorporated into an adeno-associated virus serotype 2 [Agent Trade Name] in hopes of protecting and possibly generating dopamine-producing neurons initially in four patient volunteers with Parkinson's disease. He stated that this project is a safety and preliminary efficiency study of [Agent Trade Name] that will utilize two doses. Reviewer provided a brief overview of the application which he stated was complete and thorough, in addition, he lead a detailed discussion of the RAC review comments provided to the PI and the PI's response to the RAC. The IBC concurred that the PI should submit for review by the IBC, the modified informed consent document as requested by the RAC. In addition, the IBC concurred that the PI must confirm that appropriate members of the research team have completed the Rush "shipment of dangerous goods" training. After some additional discussion, a motion was made, seconded and passed to approve this application pending the submission of the clarifications discussed above.

Provisional Approval Motion: Dr. J. Oswald; Second: Mr. T. Green; Vote: For: 6; Against: 0; Abstain: 1

6. New Discussion

Dr. W. Knudson stated that he would like additional IBC members to review protocols, including a virologist and other faculty members that he would like to recruit. The IBC concurred that he should do so.

7. Meeting adjourned at 1:10 pm. Motion: Dr. W. Knudson; Seconded: Dr. J. Oswald; Voted: For: 7; Against: 0; Abstain: 0

Minutes submitted by: V. Berry

Meeting Minutes July 28, 2005**Present:**

J. Bremer, Ph.D.
 M. Bowman, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M
 A. Tenorio, M.D.
 L. Brodsky, M.P.H.
 T. Green
 E. Sondergaard
 W. Knudson, Ph.D.

Absent:

S. Pur, R.N., B.S.N
 D. Clark, Ph.D.

The meeting was called to order at 11:10 am

1. The minutes for the May 26, 2005 IBC meeting were approved with the following corrections: the responsibilities of the Biosafety Officer should include "...conducting inspections of and monitoring activities in the laboratories" in item #2. Various typographical errors should be corrected. Motion: E. Sondergaard; Seconded: Dr. S-P. Kwan; Vote: For: 8; Against: 0; Abstention: 0
2. Dr. W. Knudson noted that V. Berry has left Rush for a new work opportunity and that D. Haywood would be administrating the IBC until the vacant position is filled.

The IBC concurred with the expedited review and approval since May 26, 2005.

	ORA#	TITLE
J. Kerns	05060312	Repair of the Partial Nerve Lesion: an Experimental Model

9. The IBC concurred with the applications approved after PI made changes requested by the IBC:

Investigator	ORA #	TITLE
J. Bremer	05050601	Generation of Standards for Use with Molecular Assays
L. Verhagen	05033101	A Phase I, Open-Label Study of [Agent Trade Name] (Adeno-Associated Virus Serotype 2 (AAV2)-Neurturin (NTN) to Assess the Safety and Tolerability of Intrastriatal Delivery to Subject With Idiopathic Parkinson's Disease [Protocol No.]

10. New/Tabled IBC Applications for Full Committee Review

Investigator	ORA#	TITLE
G. Schaer	05051102	A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multi-center, Dose-selection of Ad2/Hypoxia Inducible Factor (HIF1 α /VPI6) in Patients with Intermittent Claudication-Walk Study [Protocol number]

Discussion of ORA# 05051102

It was the consensus of the Committee that the PI had done a good job in responding to the concerns and clarifications requested by the IBC in the letter dated June 2, 2005. The PI provided a map of the construct, lab rules, the patient consent document and the correspondence from the RAC to the sponsor, in addition to responses to the other clarifications requested. Flu-like symptoms are the most common SAE reported to IBC when utilizing an adeno-associated viral vector. The Laboratory Safety Officer will assure that all personnel in the laboratory will complete the required HES Laboratory Safety training module. Any approval letter of this application should include a reminder to the PI to submit a final copy of the study patient consent document to the OBA. After some additional discussion, a motion was made, seconded and passed to approve this application.

Motion to Approve: Dr. S-P. Kwan; Second: Dr. N. Lurain; Vote: For: 8; Against: 0; Abstention: 0

11. The IBC concurred with the notification of annual renewals.

Investigator	ORA #	TITLE
F. Cohen	82051941	Molecular Biophysics and Physiology

12. Old Business

Additional members of the IBC are being sought. The names of 5 potential members were discussed. Drs. W. Knudson and J. Oswald will follow-up with these individuals to determine whether they would be willing and eligible to serve on the IBC. The term of service for IBC members remains undecided.

13. New Business

Review of UIC's "Human Gene Transfer Review" Form. IBC members reviewed the "Human Gene Transfer Review" form used by the UIC IBC to document their review of such IBC applications. There was considerable discussion over whether review of the patient consent document should be reviewed by the IBC or simply requested and maintained on file. There should be an ability to identify IRB correspondence to the PI that would significantly impact the review of the consent document by the IBC. After some additional discussion, the IBC concurred that Drs. W. Knudson and J. Oswald should revise the document in question to reflect Rush IBC concerns and re-present the document to the IBC for further consideration.

Release of IBC Minutes to Non-members. Dr. W. Knudson had received a request by a PI to obtain the minutes from an IBC meeting at which his/her IBC application was discussed. Dr. W. Knudson corresponded with Dr. D. Clark, the Director of Research Compliance, who noted that although it seems warranted for the IRB and IBC to share minutes, it may not be appropriate for either committee to share their minutes directly with PIs. The NIH Guidelines require the dissemination of IBC meeting minutes to the public upon request and that a PI could be considered a member of the public. The IBC concurred that requests of minutes and other confidential IBC information would be considered on a per case basis. It was further noted that Dr. J. Mulshine, the new Associate Provost for Research, should address the interplay and sharing of information between the Institution's regulatory committees including the IRBs, IBC, and IACUC.

IBC Application. The current, revised version of the IBC application is not yet posted on the Associate Vice President for Research website. Drs. W. Knudson and J. Oswald and D. Haywood would look into this and assure that the appropriate version of the application form is posted.

12. Meeting adjourned at 12:14 pm: Motion: Dr. J. Oswald; Second: Dr. J. Bremer; Vote: For: 10; Against: 0; Abstentions: 0

Minutes submitted by: J. Oswald, D.V.M.

Meeting Minutes January 26, 2006**Present:**

E. Sondergaard
 T. Green
 W. Knudson, Ph.D.
 J. Oswald, D.V.M
 S-P. Kwan, Ph.D.
 A. Tenorio, M.D.
 N. Lurain, Ph.D.

Absent:

L. Brodsky, M.P.H.
 L. Valentino, M.D
 S. Pur, R.N., B.S.N
 J. Bremer, Ph.D.
 M. Bowman, Ph.D.

The meeting was called to order at 11:15 am

The minutes for the July 28, 2005, IBC meeting were approved.: Motion: Dr. J. Oswald; Second: Drs. N. Lurain & A. Tenorio; Vote: For: 7; Against: 0; Abstention: 0

The IBC concurred with the applications receiving expedited review and approval since July 28, 2005:

Investigator	ORA#	TITLE
Y. Murad	05081909	In Vitro and In Vivo Characterization of Link Protein-3 (LP3)
C. Forsyth	04092803	Metalloprotease-EGFR Regulation of Intestinal Barrier
L. Thomas	04122804	Neutrophils and HIV-1 Infection
A. Jaramillo	05081103	Characterization of the Cytotoxic CDB+ T Cell Immune Response to Mammaglobin-A

The IBC concurred with the applications receiving annual renewal since July 28, 2005:

Investigator	ORA #	TITLE
G. Schaer	04021003	A Multi-center Randomized Double Blind Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered via [Company Name] Stiletto Endocardial Injection Catheter pVGI.1 (VEGF2) (Placebo, 20, 200, or 800 µg) In Patients with Class III or IV Angina with an Option for Patients to Receive Active Treatment at One Year If They Experience a Treatment Failure

Old Business

Dr. J. Mulshine had invited a consultant group to meet with various members of Rush research administration including Drs. W. Knudson and J. Oswald and the Occupational Safety group to evaluate various aspects of the IBC, including the need for an Institutional Biosafety Officer (BSO). A draft of the consultants' report should be available by the week of February 6, 2006 and this report will be relayed to the IBC.

New Business

Dr. W. Knudson announced that he will be leaving Rush as of March 1, 2006 and that Dr. J. Mulshine will be appointing an interim chairperson to the IBC until the consultants' report is received and evaluated. There was some discussion regarding the selection of the interim IBC chairperson. It was also noted that the IBC administrative coordinator had left Rush and that D. Haywood would administer the IBC until the vacant position is filled.

- IBC members discussed general IBC membership and participation. It was noted that many faculty members are leaving Rush, that faculty participation on regulatory committees is becoming onerous, and that Dr. J. Mulshine should be made aware of these concerns.

(Dr. A. Tenorio arrived at the meeting.)

- It was the consensus of the IBC that when new IBC members are appointed, they should receive training information from the chairperson and the CRC administrative staff.
- Ms. D. Haywood will send and receive IBC application reviewer comment sheets via electronic mail to facilitate the review process. IBC members discussed the current 2-week deadline of IBC submissions prior to review at the next meeting. The deadline may be extended to 3 weeks if the reviewing task becomes too onerous.

Adjournment: Meeting adjourned at 11:52 am: Motion: Dr. J. Oswald; Second: Dr. W. Knudson; Vote: For: 7; Against: 0; Abstention: 0

Minutes submitted by: J. Oswald, D.V.M.

Meeting Minutes September 28, 2006**Present:**

J. Bremer, Ph.D.
 S. Pur, R.N., B.S.N.
 M. Bowman, Ph.D.
 S-P. Kwan, Ph.D.
 N. Lurain, Ph.D.
 J. Oswald, D.V.M
 A. Tenorio, M.D.
 L. Brodsky, M.P.H.
 T. Green
 E. Sondergaard
 A. Viridi, Ph.D.
 E. Blazek, Ph.D.

Absent:

L. Valentino, M.D.

The meeting was called to order at 11:10am. The minutes from the January 26, 2006 IBC meeting were approved. Motion: Dr. J. Oswald; Second: Dr. N. Lurain: Vote: For: 6; Against: 0; Abstention: 2

The IBC concurred with the applications receiving expedited review and approval since January 26, 2006:

Investigator	ORA#	TITLE

The IBC concurred with the applications receiving approval after PI made changes requested by the IBC since January 26, 2006:

Investigator	ORA #	TITLE
A. Aroutcheva, Ph.D.	06021515	Natural antimicrobials against bacterial vaginosis
X. Xu, Ph.D.	05100301	Pathogenic role of heparanase in pancreatic cancer-medicated proteinuria
X. Xu, Ph.D.	05111601	Uric Acid Crystals as a novel Adjuvant for HER-2/neu-based Immunotherapy in a Somatic Mammary Carcinoma Model
J. Kordower, Ph.D.	05072801	Gene Therapy in a Genetic Nonhuman Primate Model of Huntington's Disease
R. Sumner, Ph.D.	06050302	Adenovirus based gene transfer for bone implant fixation
X. Xu, Ph.D.	06080102	Role of heparanase-1(HPR1) in breast tumor angiogenesis growth
G. Spear, Ph.D.*	06080205	Evolutionary Lead Optimization for Immunotherapy of Marburg and Ebola Viruses

*It was noted that the Spear proposal above involves the transfer of genes for viral capsid proteins into a defective vector for a cell culture system. Complete infectious virus particles cannot be generated.

The IBC concurred with the new IBC Applications since January 26, 2006:

Investigator	ORA #	TITLE	
K. Pahan	06082105	Statin and phenyl acetate in MPTP mouse model [Protocol No.]	

The Committee's previous concern that a treatment protocol be established for any individual inadvertently exposed to MPTP has been satisfactorily addressed by the PI and his department.

The IBC concurred with the applications receiving annual renewal since January 26, 2006:

Investigator	ORA #	TITLE
F. Cohen	82051941	A Model System for Physiological Exocytosis
G. Spear	03052002	Activation of Innate Immunity by Filovirus Glycoproteins
J. Bremer	05050601	Generation of Standards for Use with Molecular Assays
G. Andersson	01060401	Intervertebral Disc Degeneration and Regeneration
L. Verhagen	05033101	A Phase I, Open-Label Study of [Agent Trade Name] Adeno-Associated Virus Serotype 2 (AAV2)- Neuturin (NTN) to Assess the Safety and Tolerability of Intrastriatal Delivery to Subject with Idiopathic Parkinson's Disease [Protocol No.]
G. Schaer	04021003	A Multicenter, Randomized, Double-blind, Dose Ranging Placebo-Controlled Study Evaluating Defined Doses of Percutaneously Delivered via [Company Name] Stiletto™ Endocardial Injection Catheter pVGI.1(VEGF2) (placebo, 20, 200, or 800 mg) In Patients With Class III or IV Angina

1. Old Business: None.
2. New Business:

(Dr. A. Tenorio and Ms. S. Pur arrived at the meeting.)

An administrative error was made whereby the principal investigator of a particular IBC application was inadvertently made aware of the IBC member reviewers of the application. This was disconcerting to the reviewers. This error was recognized and steps have been taken to assure that this error does not recur.

There was a discussion about the present IBC application distribution and review process. The IBC concurred that new applications will continue to be directed to the IBC chairperson, who will assign review of the application to the Biological Safety Officer (BSO), whose appointment is imminent, and to IBC member scientists. The comments and recommendations of these individuals will be included on the agenda for the next IBC meeting (currently scheduled for November 30) for discussion of all applications submitted from today until November 23. The IBC concurred that the process should be re-evaluated and discussed at the next convened meeting.

Dr. A. Viridi was introduced as the new IBC Chairperson.

3. Adjournment: Motion: Dr. J. Bremer; Second: Dr. J. Oswald; Vote: For: 10; Against: 0; Abstention: 0. Minutes submitted by: J. Oswald, D.V.M.