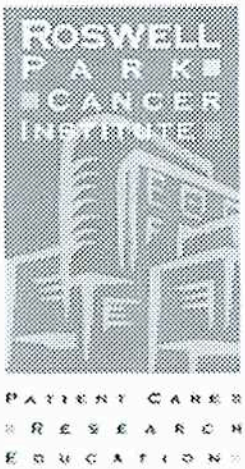

Camille P. Wicher, Esq., RN, MSN.
Assistant Vice President
Office Research Subject Protections/Institute Official
Roswell Park Cancer Institute
Elm & Carlton Sts
Buffalo, New York 14263
Phone: 716-845-7647
Fax: 716-845-5940
e-mail: camille.wicher@roswellpark.org

POSTMARK 10/01

November 1, 2006

Edward Hammond
The Sunshine Project
PO Box 41987
Austin TX 78704

RE: Attached e-mail request of 10/13/06

Mr. Hammond,

Enclosed please find minutes from the RPCI Biosafety committee as per your request.

Sincerely,

Camille P. Wicher Esq., RN, MSN
Assistant Vice President
Office of Research Subject Protections

cc. Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892-7985

From: Edward Hammond [mailto:hammond@sunshine-project.org]
Sent: Fri 10/13/2006 1:10 PM
To: Karuza, Colleen; Rustum, Youcef; Epstein, Judith
Subject: IBC Minutes request

Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo NY 14263

To Whom It May Concern:

Please read this letter carefully. It pertains to important obligations of Roswell Park Cancer Institute and to a federal complaint that the Sunshine Project may lodge against it. It is important that Roswell Park Cancer Institute reply.

More than six months ago, the Sunshine Project requested minutes of the Roswell Park Cancer Institute Institutional Biosafety Committee (IBC). Although release of the minutes is mandatory under the NIH Guidelines for Research Involving Recombinant DNA Molecules, minutes have not been received from your institution.

This letter is to reiterate the Sunshine Project's request for the Roswell Park Cancer Institute IBC minutes (from 1 May 2003 through the present). If you do not provide the requested minutes by November 6th, the Sunshine Project will immediately lodge a complaint with the National Institutes of Health. This complaint could result in a loss of research funding for your institution.

The following two situations apply to some institutions receiving this letter:

Excessive Fees: Some institutions have conditioned public access to their minutes upon payment of exorbitant fees. It is our policy to pay reasonable fees for copies and postage (from a few dollars up to about $30, depending on the volume of minutes). Higher fees constitute an impediment to public access that is not permitted by the NIH Guidelines. If copying or mailing is difficult or expensive for you, please send the requested records by e-mail.

No FOIA Requests: The NIH Guidelines do not require the Sunshine

Project to file a FOIA request (state or federal) in order to obtain your IBC minutes. The NIH Guidelines do require that you make your minutes available to the public. If you wish to have your FOIA officer or another official handle the request, we do not object in principle. In such a case, forward this request to the appropriate official(s). If you continue to refuse to honor a request made under the Public Access Provisions of the NIH Guidelines, the Sunshine Project will lodge a complaint with NIH.

If you provided some of the requested minutes in response to the Sunshine Project's 2004 survey of IBCs, it is not necessary to provide a second copy. If applicable, please make note of this situation in your reply.

The Sunshine Project's permanent address is PO Box 41987 Austin, TX, however, in order to expedite receipt of your response, please send your reply to this letter to:

Edward Hammond
The Sunshine Project
1920 Stuart St
Berkeley CA 94703

As always, the Sunshine Project is happy to receive the requested minutes by e-mail or to download them from a public URL that you provide.

Thank you for your prompt attention to this request.

Sincerely,

Edward Hammond

MINUTES

Institute Biosafety Committee

December 13, 2002

PRESENT: Drs. Casperson, Kozbor; Mr. Holden, Bradford; Ms. Wicher
Excused: Drs. Loverde; Thanavala; Becker
Staff: Ms. Dewey

I. Introduction of Members

The members of the committee were introduced. Currently, Ms. Wicher is functioning as chair.

II. Presentation –

The NIH guidelines for IBC and a copy of the PowerPoint slides were handed out. The IBC presentation followed. (See attached)

III. Role and Function

The committee has been appointed by Dr. Hohn, President and CEO in order to fulfill the requirements of the NIH for recombinant DNA research. This committee will have an integral relationship between the IRB, IACUC and the Radiation Safety Committee.

There was a discussion as to whether or not we need other members to have the on the committee in order to have the necessary expertise to fulfill our function. It was suggested that Dr. Martin Mahoney serve on the committee. Rick Holden knows a person with environmental expertise (Jonathan), who has served as a consultant to the Institute in the past, who would be a good addition to the committee. Mr. Owens may also be needed as a regular or ad hoc member for safety issues.

The IBC will be registered with the Office of Biotechnology Activities (OBA) and an annual report will be submitted to them on RPCI activities. Under NIH guidelines, IBC minutes are to be publicly available.

Will discuss additional members with Dr. Hohn.

IV. SOP's

Since IBC's are established in several places around the country, it was suggested that we review other IBC manuals and/or material if possible so that we are not reinventing the wheel. Dr. Kozbor had several suggestions and may have

documents that we can review and adapt or utilize in formulating our own SOP's. In addition, it was suggested that since the University has a functioning committee, and Dr. Loverde is a member of our committee as well, he may be able to assist in providing guidelines and/or samples of forms which could be used here. Ms. Wicher will contact him in this regard. It was felt that an easier, user friendly version of the NIH guidelines, which might be obtained through the CDC should be obtained and circulated for use by the members.

The committee needs to consider education for members and for PI's, forms, and a database to keep information. A process for monitoring protocols and for sanction where guidelines are not followed need to be put into place.

It was felt that we should meet monthly to review protocols, and maybe quarterly as a committee for process purposes. In addition, Ms. Wicher suggested that an appropriate co-chair be appointed.

V. Committee

Currently, there are 3 animal protocols waiting for our review. There is 1 human protocol currently monitored by an outside IBC. The RPCI IBC can assume responsibility for this protocol when we are functionally able to do so.

Ms. Wicher will poll the members to see if Friday at noon (a lunch meeting) is convenient for the members.

VI. Other

Ms. Wicher will circulate the information from this meeting. Any information or guidance from the members will be appreciated.

Members should review the NIH guidelines.

Respectfully submitted,

s//

Camille P. Wicher, Esq. RN, MSN

Institute Biosafety Committee

MINUTES: January 27, 2003

I. Membership

Mr. Owens will be added as an ad-hoc member; Dr. Segal as the Infectious Disease Physician will be asked to become a member. We will need to have another layperson on the committee. A social worker or religious were recommended to give depth to the committee.

II. Role and Function

There was a great deal of discussion on what the committee is going to be responsible for and have authority over. Before we can have a co-chair, the committee would like to determine the focus of the committee. A suggestion was made to poll the research community at RPCI to determine what their needs are with regard to recombinant DAN research and use of the NIH/CDC biohazard agents so that we may focus the committee and the resources. An inquiry will be made as to the short term and long term needs in this regard.
A second suggestion was made to contact our colleagues at, for example, MSK and MD Anderson for information and any SOP's that might be shared for our use here.

III. SOP's – these need to be developed after we determine what the focus of the committee will be. Will we review only recombinant DNA? What type of agents does the committee want to review? What type should we review? Do we want chemical agents reviewed? Viruses?

There needs to also be a procedure and forms developed for the interaction between the various oversight committees, (IRB, IACUC, IBC) as well as a definition of the process. Will we review everything as a committee? Will only certain types of protocols or Biosafety levels come for full committee review?

IV. Education:

How will we educate the committee members and the PI's? Dr. Loverde suggested the CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition as a guide. It is available on the internet at http://www.cdc.gov/od/ohs/biosafty/bmbl4s1.htm. I have ordered 10 copies for committee members.

V. Other

Existing RPCI Policies and Procedures that may govern biosafety were handed out to the members of the committee for review.

Both Drs. Kozbor and Loverde have supplied information/manuals that they have used in the past in order to use as guidelines in developing the committee's documentation.

Given the Core Grant site visit on February 13, 2003, we will schedule the next meeting for early March, depending on the member's schedules.

S/1

AGENDA

Institute Biosafety Committee

December 18, 2003

PRESENT: Drs. Loverdi, Thanavala, Kozbor and Becker; Mr. Owens, Fr. Mattimore, Ms. Wicher

Staff: Ms. Dewey

I. Members

Dr. Rustum is in the process of appointing a chair. Dr. Yates has been asked. MS. Wicher to meet with Dr. Yates and review the progress of the committee up to this point.

II. Review of Submissions

The submission form needs revision. Various members had constructive criticism of the form, which will be revised. Based on the ambiguity of the form, the submission forms were not always accurately completed. The committee considered the submissions nevertheless.

1. Dr. Sosse-Aaoui - IACUC protocol P962 M - approved pending modification to the form to accurately reflect the research.
2. Dr. Yu – "Engineering knockouts and knock ins in mice to Model Human Cancers" – approved pending modification to the form to accurately reflect the research.
3. Dr. Lin: IACUC protocol P954M: denied. The investigator will be asked to submit appropriate documentation regarding the use of the gene delivery system.
4. Dr. Thanavala: Add on for review: After much discussion, it was determined that the investigator will not use the biohazard proposed in this submission. The investigator has frozen stocks and if the PI decides to use them, the project will be resubmitted for review. In the event that this is resubmitted the IBC requests that the PI include the following:
    a. Identify the dose to be used in the animals.
    b. Describe whether or not only vaccina will be used, which constitutes no biohazard; or identify the plasmids used and the cells to be grown, as this may constitute a hazard.
    c. If the biohazardous form is to be used, include the hazard and the precautions to protect personnel consistent with the CDC and NIH guidelines, including the need to offer vaccination, if applicable.

III. Other Issues

1. Do we need to revise our forms? Yes. This will be done within the next month.

2. We will be responsible for over sight of the MUA for IACUC protocols – this form may also need revision. A formal procedure will be requested from Dr. Rustum for assuming responsibility for this review.
3. Other:
    a. the timing of Biosafety review was discussed in relation to other committee oversight, namely IRB and IACUC. It was determined that the Biosafety review should precede the IRB/IACUC review.
    b. A separate Website area should be available for the forms, policies, procedures, etc.

5//

Institute Biosafety Committee

Meeting Minutes March 25, 2004
Meeting called to order with quarum present at 1: 05 pm.

PRESENT: Drs. Yates, Thanavala, Kozbor, Becker, Messrs. Bradford, Owens, Ms. Wicher

Staff: Dewey

I. New Chair

Introduced Dr. Yates to the committee. Dr. Yates will serve as chair of the committee. Ms. Wicher will provide administrative support

II. A. **Review of Submissions**

1. Dr. Odunsi: HUMAN PROTOCOL I:*13303: Phase II Study of Recombinant Vaccinia-NY-EOS-1 and Recombinant FowlPox-NY-ESO-1 in Patients with Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma Whose Tumors Express NY-ESO-1 or LAGE-1 Antigen.*
Discussion centered around the use of Vaccinia and the hazards to the patients and the administrators of the vaccine.

DECISION: Deferred pending further information.

2. Dr. Chadha: *IACUC Protocol 970M: Role of MMP-9 In Prostate Tumor Metastasis:*

DECISION: Approved

3. Dr. Lin: *IACUC protocol P954M: The investigator has now submitted documentation regarding the use of the gene delivery system and the protocol this is to be used under 954M: Evaluation of Tumorigenicity of cells in Mice:*

DECISION: Approved

B. **Expedited/Exempt**

The following were reviewed by The Chair of the committee in an expedited manner:

1. Dr. Wang: *IACUC protocol 981M: Evaluation of Stress Protein Grp 170-based Melanoma Cancer Vaccines* BSL 1:

DECISION: EXEMPT

2. Dr. Fenstermaker: *IACUC protocol 982M: Development of anti-glioma vaccines in mice.* BSL 2:

DECISION: Exempt

III. Other Issues

1. MUA's will no longer be reviewed by Dr. Rustum. All MUA's will come to the Office of Research Subject Protoection to be reviewed by the Chair IBC or designeee (Dr. Becker). IACUC and the PI's will be notified.
2. Other:
    a. OBA documents:
        i. FAQ's about Recombinant DNA
        ii. Guidance on Informed Consent.
        iii. A separate Website area should be available for the forms, policies, procedures, etc. – in the process
3. Application Form:

    Applications forms form Pittsburg, Stanford, VA were submitted for review by the committee.. The committee uanimously voted for the format and content as followed by the Univ. of Pitt. This format will be adapted for use here at RPCI.

4. Submission:

    The committee would like the applications, the MUA's to be aviaable on line and submitted electronically for review. Ms. Wicher will work with IT to get this accomplished.

No other business, the meeting was adjourned at approxzimately 2:15 pm.

Minutes compiled by Ms. Wicher

S//

Minutes of the Institute Biosafety Committee Meeting
February 17, 2005
Convened at: 1:00 p.m. and Adjourned at 2:00 p.m.

Present: Drs. John Yates (Chair), Becker, Kozbor, Segal and Thanavala, Mr. Borzynski and Rev. Mattimore

Absent: None

ORSP Staff: Ms. Kraemer, Ms. Simon and Ms. Wicher

Old Business

No old business was reviewed.

New Business

1.) Introduced Mr. Borzynski.
2.) Reviewed history of GenVec Study.
3.) IBC e-mail review and approval 1/05: CE 04-05, Dr. Odunsi, entitled, "Recombinant Vaccinia-NY-EOS-1 and Recombinant FowlPox-NY-ESO-1 (rV-NY-ESO-1) for Metastatic Breast Cancer Whose Tumors Express NY-ESO-1 or LAGE-1" was reviewed.
4.) FORMAT:
   - In the future – all submissions should be paginated.
   - A summary of all the changes/amendments during the year should be included up front so that the committee can see these more easily.
   - Changes to help clarify the review will be made on the submission form.
5.) VACCINIA: clarify with the CDC whether those in the laboratory and pharmacy who are mixing or preparing the agent should be offered the vaccine.

   Perhaps, even if the vaccination is not required, we can make it available for those who would like to be immunized.

Review of Submissions

1.) **PH 43604**, Dr. Javle, entitled, "A Phase III Randomized, Controlled Study to Evaluate the Safety and Efficacy of PANVAC - VF in Combination with GM-CSF Versus Best Supportive Care or Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of he Pancreas Who Have Failed a Gemcitabine-Containing Chemotherapy Regimen"
   a. Initial submission

   Decision: **DEFERRED**

2.) **DS 02-14**, Dr. Javle, entitled, "A Randomized, Phase II, Study of TNFerade Biologic with 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer"

   In the past, the WIRB IBC has been responsible for reviewing and approving biosafety issues on this study. However, this study now needs review under the RPCI IBC.
   a. Amendment of 8/5/2004 (reviewed and approved by IRB 10/19/04, no patient accrual since amendment approval).
   b. MSDS of 6/9/04 (reviewed by IRB 6/28/04).

c. Continuing Review to include site review and protocol review (subcommittee required to inspect site including pharmacy and product storage facility after meeting).
d. Provide information how many antigen(s) are expressed by one recombinant vaccine virus.

Decision: **APPROVED PENDING**

3.) **I 13303** (IBC 04303), Dr. Odunsi, "Phase II Study of Recombinant Vaccinia-NY-EOS-1 and Recombinant FowlPox-NY-ESO-1 in Patients with Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma Whose Tumors Express NY-ESO-1 or LAGE-1 Antigen"
a. Continuing Review to include site review and protocol review.
b. Amendments approved during the year.

Decision: **APPROVED PENDING**

4.) **961M** (IBC 031203), Dr. Yu, entitled, "Engineering Knockouts and Knockins in Mice to Model Human Cancers"
a. Deleted on 1/14/05.

5.) **962M** (IBC 031202), Dr. Sossey-Alaoui, entitled, "Genetic Engineering of Mice to Develop an Animal Model for Neuroblastoma"
a. Annual review – 11/24/04.

Decision: **APPROVED**

Other Issues

1.) ORSP is in the process of updating our website.

Several new or revised items/forms are to be reviewed for the next meeting.

- Annual Review – Human Subjects form
- Expedited form
- Exempt form
- Adverse Event Template (from the NIH website) FAQ's
- FAQ's
- How to submit and application
- How to comply with Appendix M
- Mission Statement
- Overview of Biosafety levels 1-4

Respectfully Submitted,

SII

Camille P. Wicher, ESQ., RN, MSN
Administrative Director, Office
Research Subject Protection

Minutes of the Institute Biosafety Committee Meeting
April 21, 2005
Convened at: 1:00 p.m. and Adjourned at 2:15

Present: Drs. Almyroudis (Co-chair), Becker, Ciesielski, Kozbor (Co-chair), Mahoney and Thanavala, Mr. Borzynski and Mr. Moslow

Absent: Rev. Mattimore

ORSP Staff: Ms. Kraemer, Ms. Simon and Ms. Wicher

Old Business

1. **PH 43604**, Dr. Javle, entitled, "A Phase III Randomized, Controlled Study to Evaluate the Safety and Efficacy of PANVAC - VF in Combination with GM-CSF Versus Best Supportive Care or Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of he Pancreas Who Have Failed a Gemcitabine-Containing Chemotherapy Regimen"

   -Response to clarifications for initial submission were reviewed and approved.

2. **I 13303**, Dr. Odunsi, entitled, "Phase II Study of Recombinant Vaccinia-NY-ESO-1 (rV-NY-ESO-1) and Recombinant Fowlpox-NY-ESO-1 (rf-NY-ESO-1) in Patients with Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma Whose Tumors Express NY-ESO-1 or LAGE-1 Antigen"

   -Response to clarifications for continuing review were reviewed and approved.

New Business

1. **DS 02-14**, Dr. Javle, entitled, "A Randomized, Phase II, Study of TNFerade Biologic with 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer"

   -Review of safety reports; no changes requested by this committee, will defer to the IRB

2. **CE 05-02**, Dr. Odunsi, entitled, "Vaccination with Recombinant Fowlpox-NY-ESO-1 (rF-NY-ESO-1) in a Single Patient with Retroperitoneal leiomyosarcoma Whose Tumor Expresses NY-ESO-1 and LAGE-1 Antigen"

   -Review of single patient IND:

   Several minor points of clarification requested.

3. Review of application forms for revision.

   -several changes recommended in the forms. These will be done as soon as possible with the goal to have the forms available on the web for use by PI's.

4. Dr. Ionov's submission IACUC protocol 991M:
   Discussion centered on what role OES plays in oversight of lab. It was decided that where chemical hazards or questions arise OES would review the application to determine if acceptable. Then application would be reviewed by IBC.

5. Discussed emergency phone numbers and procedure for after hour incidents. Mr. Moslow will put together a procedure based on the existing emergency after hours procedures for incidents and recommendations will be made based on this document.

Review of Submissions

None

Approved Protocols in March 2005 – Expedited

1. IACUC
   954M Renewal
   982M Renewal

5. IRB None

5/11

Minutes of the Institute Biosafety Committee Meeting
June 20, 2005
Convened at: 1:00 p.m. and Adjourned at 2:15 p.m.

Present: Drs. Kozbor (Co-chair), Almyroudis (Co-chair) and Thanavala, and Mr. Borzynski

Absent: Drs. Becker, Ciesielski, and Mahoney and Mr. Moslow

ORSP Staff: Ms. Simon and Ms. Wicher

Old Business

1.) The Institute Biosafety Committee Meeting Minutes of April 21, 2005 were reviewed and approved via e-mail.

New Business

1.) **DS 02-14**, Dr. Javle, entitled, "A Randomized, Phase II, Study of TNFerade Biologic with 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer"

-Review of amendment #5

In the exclusion criteria, section 5.2.2 an addition was made to exclude patients currently receiving hormone replacement therapy. Please clarify which hormones are included, i.e., does this apply to patients taking thyroid medication?

In addition, if a patient were on HRT, how long would they have to be off of HRT in order to be considered eligible for this study?

DECISION: APPROVED PENDING

2.) Review of application forms for revision. Dr. Kozbor will meet with Juliet Kraemer to finalize the changes recommended by the committee. The forms will then be posted on the RPCI internal website.

3.) Review of adverse events (see attached report):
The committee is not requiring any changes to the informed consents.

4.) The committee would like the IRB to consider requiring a statement on the last page of all consent forms under "Statement of Consent," indicating, "You understand there are risks to being on this study and they have been explained to you."

Review of Submissions

None

Informational:

Approved IACUC Protocols – Expedited

050302	4/2/2005	Fenstermaker
050401	4/21/2005	Foster
050402	5/15/2005	Chadha

050502	5/15/2005	Foster
31204	5/18/2005	Lin
050503	5/20/2005	Brattain
050504	5/26/2005	Repasky
050506	5/31/2005	Wang, XH
050505	5/31/2005	Wang, XH

Approved Grants – Expedited

050501	5/8/2005	Goodrich

Respectfully Submitted,

S//

Camille P. Wicher, ESQ., RN, MSN
Administrative Director, Office
Research Subject Protection

Minutes of the Institute Biosafety Committee Meeting
October 20, 2005
Convened at: 1:00 p.m. and Adjourned at 2:00

Present: Drs. Almyroudis (Co-chair), Ciesielski, Kozbor (Co-chair), Harvey and Thanavala, Ms. Bowman

Absent: Mr. Borzynski

ORSP Staff: Ms. Kraemer, Ms. Speidel and Ms. Wicher

Old Business

1. The committee discussed feedback received on the revised biosafety applications and the revised MUA application. Forms have been posted to the IBC, IACUC, IRB and Safety websites. Submissions on the old versions of the applications are now outdated and will not be accepted for review by the committee. Feedback has been positive, PIs questions are easily addressed, and the process for submission and review is working efficiently.

2. The committee agreed to minor revisions of the MUA that would increase consistency between sections, coincide with published hazards, and hopefully further direct and assist PIs in completely the application.

3. Dr. Harvey reported on the status of developing and implementing a procedure for posting emergency numbers and PI/personnel contact information in labs, for use in the case of an emergency. It is in progress and expects to have a policy enforced within the next couple of months.

4. Dr. Kozbor suggested posting Biohazard signs as needed on laboratory doors, etc. throughout the Institute. To ensure understanding of the signs, Dr. Harvey would like to add biosafety training to the new employee orientation before the signs are posted.

New Business

1. The new lay committee member, Jeanne Bowman, was introduced to the committee.

2. PIs submitting an initial biosafety application that involves human cells/tissue samples will also need to submit an MUA. PIs doing in vitro work involving human cells/tissues will also need to submit a biosafety application and an MUA.

Review of Submissions:

None

Approved IACUC Protocols:

Protocol	PI	ID	Approval Date
828	Cowell	040703 (R)	8/14/2005
836	Cowell	040702 (R)	8/14/2005
1018	Kozbor	040902 (R)	9/9/2005
1020	Kozbor	041001 (R)	9/9/2005
1037	Zhang	050901 (N)	9/15/2005
891	Foster	050902 (N)	9/23/2005

075 Henderson 050903 (N) 9/30/2005

IRB Informational:

Protocol	PI	ID	Approved	Approval Date
DS 02-14	Dr. Javle	020401	Recruitment Materials	9/2/05
DS 02-14	Dr. Javle	020401	Patient Diary Pages	9/8/05
PH 43604	Dr. Javle	041101	Self Administration Form	9/15/05
PH 43604	Dr. Javle	041101	Sponsor Web Permission Patient Information Card	9/16/05

5/1

Minutes of the Institute Biosafety Committee Meeting
December 15, 2005
Convened at: 1:00 p.m. and Adjourned at 2:30

Present: Drs. Almyroudis (Co-chair), Mahoney, Becker, Kozbor (Co-chair), Harvey and Thanavala, Ms. Bowman, Mr. Borzynski,

Absent: Dr. Ciesielski

ORSP Staff: Ms. Kraemer and Ms. Wicher

Old Business

1. Dr. Harvey and Ms. Kraemer will design biohazard signs to post throughout the institute on doors of laboratories that are using biohazardous material. The sign will include emergency contact information. The sign will be distributed to the committee for review and approval via email, then distributed to PIs for posting.

New Business

1. Meeting dates for 2006 were confirmed; the committee will continue to meet as needed with scheduled meetings on the third Thursday of every other month.

2. Ms. Wicher and Ms. Kraemer will be preparing a brief presentation on the role of the IBC and will present at the February IBC meeting.

3. Drs. Kozbor and Harvey are working on a biosafety manual. Once finalized, they will implement a training program.

4. Dr. Kozbor opened up discussion on the possibility of establishing a BSL3 facility at Roswell Park. Committee members will meet with Dr. Rustum to discuss further and will report back to the committee at the February IBC meeting.

Review of Submissions

IBC 020401
Milind Javle; Continuing Review of Biosafety Approval 020401 (IRB protocol DS 02-14; A Randomized, Phase II, Study of TNFerade Biologic with 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer)
Decision: Approved pending site inspection of pharmacy.
Vote: Unanimous.
Note: Recommendations to IRB.

IBC 041101
Milind Javle; Annual Report form Sponsor for IRB protocol PH 43604; A Phase III Randomized, Controlled, Study to Evaluate the Safety and Efficacy of PANVAC-VF....Containing Chemotherapy Regimen
Decision: Approved.
Vote: Unanimous.
Note: IBC will query IRB on dosage concerns in administering PFUs.

IBC 040303
Kunle Odunsi; Pilot Clinical Trial of NY-ESO-1 Derived Peptide of Dual MHC Class I....Whose Tumors Express NY-ESO-1 or LAGE-1

Decision: Approved.
Vote: Unanimous.
Note: None.

Approved IACUC Protocols

IBC ID	*Agent*	*Level*	*Approval Date*	*PI*	*IACUC Protocol*
051002 (N)	Chlamydia	2	10/5/2005	Wallace	1034
	rDNA	1			
051001 (N)	rDNA	1	10/5/2005	Sood	1040
051102 (N)	Aspergillus	2	11/18/2005	Segal	869
051105 (N)	rDNA	2	11/25/2005	Evans	791
051101 (N)	Aspergillus	2	11/9/2005	Segal	831
051104 (N)	retrovirus	2	11/23/2005	Plunkett	716
	rDNA	2			
051103 (N)	rDNA	2	11/23/2005	Wang	981
051106 (N)	rDNA	1	11/30/2005	Ferrone	908

Pharmacy/Site Inspection for IBC 020401/DS 02-14

IBC 020401
Milind Javle; Continuing Review of Biosafety Approval 020401 (IRB protocol DS 02-14; A Randomized, Phase II, Study of TNFerade Biologic with 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer)
Decision: Approved pending site inspection of pharmacy.
Vote: Unanimous.
Note: Recommendations to IRB.

The site is well maintained. It is a restricted access site. Entrance is by key code only.

Appropriate signage was missing in areas where biosafety work is done. The pharmacy will work with the IBC in assuring appropriate signs are acquired and displayed. There are biohazard signs, however they need to be in appropriate places and need to indicate the agent(s) in use and the biosafety level. (The investigator's name and telephone number and any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory are recommended).
The drug is not currently in stock. The sponsor has reformulated the drug and will provide an in-service when restocked. A member of the IBC will be invited to the in-service.

In order to prevent cross-contamination and ensure proper storage and handling, the pharmacy will put the drug in either a lockbox and store in the pharmacy freezer, or put it in a locked freezer kept at -20 degrees.
Pharmacy is to develop an SOP for decontamination of hoods and appropriate clean up of recombinant viruses such as vaccinia or adenovirus. All disinfectant cleaning or spray commercial agents should indicate on the label that they are "Registered with the EPA". For work that requires BSL2 practices, OSHA recommends "EPA-registered tuberculocidal disinfectants".

The site did not report any adverse events or risk situations s in the time under review.

Handwashing agents such as Iodophor surgical scrub or Hibiclens scrub are recommended in case of exposure to the virus (for example by needle stick). Also, antimicrobial handsoap should be available.

Emergency telephone number (3333) should be posted in the facility. Training record should be available to assure that persons working with infectious agents are aware of potential hazard.

Respectfully Submitted,

Camille P. Wicher, ESQ., RN, MSN
Administrative Director, Office
Research Subject Protection

Minutes of the Institute Biosafety Committee Meeting
April 20, 2006
Convened at: 1:15 p.m. and Adjourned at 2:15

Present: Drs. Becker, Kozbor (Co-chair), Harvey and Ciesielski, Mr. Borzynski, Mr. Moslow, Ms. Bowman

Absent: Dr. Thanavala, Dr. Almyroudis (Co-chair), Dr. Mahoney (excused)

ORSP Staff: Ms. Kraemer, Ms. Speidel and Ms. Wicher

Old Business

1. Dr. Harvey presented and the committee discussed the emergency contact biohazard sign. The committee approved the sign. Mr. Moslow is in the process of compiling an official contact list for all labs. Once finalized, the sign will incorporate contact information from the official list. It will then be displayed in each laboratory in a conspicuous place. The signs will be updated annually, at the time of the annual lab surveys.

2. The biosafety manual and training program are still in progress. The committee discussed purchasing an online training program through the CDC or the NIH. Mr. Moslow informed the committee that HR is implementing a database to track training requirements for all job titles; the committee will use this to ensure that all personnel requiring IBC training will receive the training. Dr. Kozbor suggested a lecture on completing the MUA and IBC applications might be helpful to PIs. The thought is to incorporate this training into the chemical hazards training classes. Ms. Wicher will research other options for online training programs. Further discussion to follow in June.

3. Dr. Kozbor updated the committee on the status of establishing a BSL3 facility at RPCI. A BSL3 facility is not possible, however efforts are still being made to convert vacant laboratory space into a BSL2+ facility. IBC members will be meeting with Steven Wright at the end of the month.

4. Ms. Kraemer will make minor revisions to the IBC and MUA applications as per request of Drs. Kozbor and Harvey. Revised forms will be presented at the June meeting for committee review and approval.

New Business

None

Minutes

February 16, 2006 meeting
Decision: Approved
Vote: Unanimous

Review of Submissions

Resubmission -
Protul Shrikant; New Submission for Amendment to IACUC Protocol 813M; "Murine Models For Immunotherapy of Cancer"
Decision: Await further information from PI before making decision

Vote: Unanimous.
Notes: The PI proposes to perform immunization studies with the attenuated Listeria monocytogenes strain 10403S that was engineered to express a secreted form of chicken ovalbumin protein (OVA), which was selected for stable expression by erythromycin resistance. The 10403S strain of L. monocytogenes is a live attenuated strain with actA and plcB gene deletions rendering this strain non fatal for B6 mice and has considerable diminished pathogenicity. The gene product of actA is responsible for actin based motility between cells, whereas the plcB gene product is an important virulence factor for the L. monocytogenes. Although, the attenuated strain has considerable reduced pathogenic potential, it may pose risk for Listeriosis in immunocompromised host, pregnant women and children, thus all BSL-2 precautions should be taken during its use.

The PI would need to provide proof that Listeria strain is an attenuated strain of Listeria.

The USDA permit for transporting the attenuated strain of Listeria to the RPCI needs to be resolved by the PI and USDA (Dr. Morris (301) 734-3277).

MUA comments
Section 4.2. Please indicate the Biological Safety Cabinet as Type II.
Section 5.2. Please indicate that all experiments with Listeria will be conducted in a BSL-2 facility with entrance restricted only to the laboratory personnel. Other personnel can be permitted to enter to the laboratory at the PI's discretion. Remove the sentence starting with "During...".
Section 6b.3. Please remove the entire paragraph starting with "During...".
Section 6b.4. Please remove the entire paragraph. Replace it with "Animal cages will be autoclaved."

IBC comments
Personnel: Please provide the information about "Contact" person.
Section 3. In the section "Will personnel work...," please remove the second paragraph starting with "Pregnant...."
Section 3 In the section "Will research studies..." please remove the entire second paragraph.
Section 5. For the Biological Safety Cabinet, please provide the date of certification.

Continuing Review
IBC 040303; K. Odunsi; (I 13303) Phase II study of recombinant vaccinia-NY-ESO-1 (rV-NY-ESO-1) and recombinant fowlpox-NY-ESO-1 (rF-NY-ESO-1) in patients with epithelial ovarian, fallopian tube or primary peritoneal carcinoma whose tumors express NY-ESO-1 or LAGE-1 antigen
Decision: Approved Pending
Vote: Unanimous
Notes:

Page iii; Dr Kepner's affiliation has been changed.
Page 1; typo "humeral"
Page 19; the paragraph "After completing ...." is repeated on page 20.

It is recommended that the rVV-contaminated bandages and towels be returned to the study site at the patient's clinic visit and that this be outlined in the consent form. The IBC also recommends including in the consent, a section that addresses activities requiring special precautions after receiving vaccinia (eg, handwashing prior to handling contact lenses).

Continuing Review
IBC 041101; Milind Javle; (PH 43604) A Phase III Randomized, Controlled Study to Evaluate the safety and Efficacy of PANVAC VF in Combination with GM-CSF Versus Best Supportive Care of Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas Who have Failed a Gemcitabine-Containing Chemotherapy Regimen
Decision: Approved Pending

Vote: Unanimous.
Notes:

Correct the IBC application section 2; one patient has withdrawn from the study.

Page 37, 7.3.2; currently states "Once used, vials, needles, and syringes should be placed in sealable plastic bags and returned at the next visit, for disposal in accordance with local procedure and biohazard and OSHA guidelines".
All needles and syringes must be carefully placed in a conveniently located puncture-resistant containers used for sharps disposal. The IBC recommends that containers be purchased and given to patients for safe storage and transport to RPCI. The containers can be purchased through Fischer Scientific (or contact OHS for vendors).

Page 41, 8.3.1.1 PANVAC-V Dose Preparation: currently state "Place the labeled syringe (containing the virus) in a plastic bag and seal. Carry the sealed bag on a tray and deliver for administration as soon as possible after preparation".
It is requested to place all contaminated syringes in a container with a cover that prevents leakage during transport, handling, or processing. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local state, or federal regulations. Ms. Kraemer contacted Dan McMillen in the Pharmacy and although the protocol states it may be transported on a tray, the pharmacy SOP is to carry the labeled syringe in a covered non-breakable container.

Approved IBC Applications for IACUC Protocols

IBC ID	Approval Date	PI	IACUC ID	Agent	BSL
060203	2/23/2006	Moser	1056	CWR22, CWR22R	2
060201	2/7/2006	Cowell	1054	MSCV	2
060202	2/15/2006	Foster	943	Tissue – Human	2
050301	3/8/2006	Wang, XY	981	Annual Renewal	1
060302	3/2/2006	Sacchi	919	Tissue – Human/Mouse Chemicals	2
060301	3/1/2006	Porter	214	Tissue – Human	2
060304	3/9/2006	Repasky	703	Tumors – Human 2	
060303	3/9/2006	Foster	943	CWR22, CWR22R	2
060305	3/30/2006	Bellnier	794	A253, FaDu	2
031204	3/6/2006	Lin	954	Annual Renewal	2

Respectfully Submitted,

5/1

Camille P. Wicher, ESQ., RN, MSN
Administrative Director, Office Research
Subject Protection

Minutes of the Institute Biosafety Committee Meeting
June 15, 2006
Convened at: 1:15 p.m. and Adjourned at 2:00

Present: Drs. Becker, Kozbor (Co-chair), Harvey, Thanavala, Mahoney, and Almyroudis (Co-chair), Mr. Borzynski, Mr. Moslow, Ms. Bowman

Absent: Dr. Ciesielski (excused)

ORSP Staff: Ms. Clark, Ms. Kraemer, Ms. Speidel and Ms. Wicher

Old Business

1. Mr. Moslow is in the process of displaying in each laboratory in a conspicuous place the emergency contact biohazard signs. The list of emergency contacts has been updated and distributed to each lab.

2. The biosafety manual and training program are still in progress. The manual is pending review and revisions to a second draft and will be brought to committee for comment at the next IBC meeting. Once the manual is finalized, formalized training can be started.

3. Dr. Kozbor updated the committee on the status of establishing a BSL2+ facility and presented materials outlining facility requirements in renovation and expenditures for supplies, although not renovations (see attached exhibits 1 - 5). The committee recognizes the need for RPCI to move forward in building a facility with higher levels of containment required for higher biosafety levels.
   The CDC guidelines formed the foundation for proposal labeled exhibit 3 (see attached) and at the moment present the most cost-effective and practical way to move forward with building the facility, however the committee recognizes the need to upgrade to NIH guidelines in the future.

   A concern is that IBC may come to understand something in the future that would require a particular lab to meet the more stringent NIH standards. IBC should ensure that the ability is preserved to act retroactively if the need arises.

   VOTE:

   The committee put forth and approved the following motion: Accept the IBC proposal based on the CDC guidelines while reserving the right to impose higher standards whenever the committee deems necessary in accordance with regulations, at any time.

4. Ms. Kraemer made revisions to the IBC and MUA applications as per request of Drs. Kozbor and Harvey.

   VOTE:

   Revised forms were discussed and approved pending minor revisions.

New Business

1. Ms. Speidel distributed an advisory dated February 4, 2004, in regard to "Information Requests from the Sunshine Project." A copy of the advisory memo is attached.

2. Due to concerns about attendance, the August IBC meeting will not be conducted as scheduled. Therefore, the next IBC meeting scheduled is October 19, 2006. However, should matters that require full committee review present, a meeting will be called prior to the October 19, 2006 meeting.

Minutes

April 20, 2006 meeting
Decision: Approved
Vote: Unanimous

Review of Submissions

Amendment -
IBC 020401; Milind Javle; (DS 02-14) A Randomized, Phase II/III, Study of TNFerade Biologic with 5-FU and Radiation Therapy for First-Line Treatment of Unresectable Locally Advanced Pancreatic Cancer
Decision: Decision: Approved pending PI clarification of use of drug erlotinib and outlining risks and side effects associated with it in the protocol and informed consent.
Vote: Unanimous
Notes: The amendment serves to move the study into Phase II as the dose escalation portion has been completed. No biosafety issues were noted.

Approved IBC Applications for IACUC Protocols

IBC ID	Approval Date	PI	IACUC ID	Agent	BSL
060401	4/4/2006	Ferrone	792B	rDNA	I
060402	4/18/2006	Repasky	927M	colo 205 cell line	II
060403	4/24/2006	Bullard-Dunn	1060M	rDNA	II
060501	5/2/2006	Rajput	920M	rDNA	II
060502	5/22/2006	Saito	1061M	lymphoma cell lines	II

Approved IBC Applications - Annual Renewals

IBC ID	Approval Date	PI	IACUC ID
050302	4/2/2006	Fenstermaker	982M
050401	4/21/2006	Foster	943M/R
050501	5/8/2006	Goodrich	Grant CA 70292
050502	5/15/2006	Foster	943M/R
050503	5/20/2006	Brattain	883M
050504	5/26/2006	Repasky	927M

Deleted IBC Applications - Project Completed

IBC ID	PI	IACUC ID
050402	Chadha	970M

Pending

IBC 040303; K. Odunsi; (I 13303) Phase II study of recombinant vaccinia-NY-ESO-1 (rV-NY-ESO-1) and recombinant fowlpox-NY-ESO-1 (rF-NY-ESO-1) in patients with epithelial ovarian, fallopian tube or primary peritoneal carcinoma whose tumors express NY-ESO-1 or LAGE-1 antigen
Decision: Approved Pending
Vote: Unanimous
Meeting: April 20, 2006
Status: Amendment has been submitted and is in review process.

IBC 041101; Milind Javle; (PH 43604) A Phase III Randomized, Controlled Study to Evaluate the safety and Efficacy of PANVAC VF in Combination with GM-CSF Versus Best Supportive Care of Palliative Chemotherapy in Patients with Metastatic (Stage IV) Adenocarcinoma of the Pancreas Who have Failed a Gemcitabine-Containing Chemotherapy Regimen

Decision: Approved Pending
Vote: Unanimous.
Meeting: April 20, 2006
Status: This study is in the process of being terminated; final report to IBC pending.

Pending; Protul Shrikant; New Submission for Amendment to IACUC Protocol 813M; "Murine Models For Immunotherapy of Cancer"

Decision: Await further information from PI before making decision
Vote: Unanimous.
Meeting: April 20, 2006
Status: PI did not respond to requested clarifications. A second notice will be sent to the PI.

Respectfully Submitted,

5/1

Camille P. Wicher, ESQ., RN, MSN
Administrative Director, Office Research
Subject Protection