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*Leading Health Care In The 21st Century*



DEPARTMENT OF VETERANS AFFAIRS  
*Samuel S. Stratton VA Medical Center*  
113 Holland Avenue, Albany, NY 12208

March 8, 2007

Mr. Edward Hammond  
The Sunshine Project  
1920 Stuart St.  
Berkeley, CA 94703

Dear Mr. Hammond:

This is in response to your Freedom of Information request concerning Recombinant DNA Molecules.

The minutes for the period of October 1, 2003 to August 2, 2006 are being withheld pursuant to 5USC 552 exemption (b)(3) as quality management documents.

Minutes of 10/1/03  
Minutes of 7/7/04  
Minutes of 1/5/05  
Minutes of 3/24/05  
Minutes of 4/6/05  
Minutes of 7/6/05  
Minutes of 10/5/05  
Minutes of 1/4/06  
Minutes of 1/18/06  
Minutes of 8/2/06

Please find enclosed the minutes that contain references to Recombinant DNA Molecules; the minutes for August 6, 2003 to April 6, 2006 are being redacted pursuant to 5USC 552 (b)(4) Trade Secrets.

Page 8 of 15 Minutes of 8/6/03  
Page 9 of 15 Minutes of 8/6/03  
Page 11 of 15 Minutes of 8/6/03  
July 14, 2003 memo attached to Minutes of 12/12/03  
October 10, 2003 letter attached to Minutes of 1/14/04

Page 4 of 24 Minutes of 4/13/04  
Page 5 of 24 Minutes of 4/13/04  
Page 13 of 24 Minutes of 4/13/04  
Page 14 of 24 Minutes of 4/13/04  
Page 15 of 24 Minutes of 4/13/04  
Page 10 of 20 Minutes 10/6/04  
Page 11 of 20 Minutes of 10/06/04  
Page 14 of 20 Minutes of 10/6/04  
Page 10 of 17 Minutes of 4/5/06

If you disagree with the above decision, you may appeal at the following address; please send a copy of this letter within 45 days:

Office of General Counsel (024)  
Department of Veterans Affairs  
810 Vermont Avenue NW  
Washington, DC 02420

Sincerely,

A handwritten signature in black ink that reads "Susan Smith". The signature is written in a cursive, flowing style.

Susan SMITH  
FOIA OFFICER

b) Section D: Chemical listing table should be in final version.

c) Section D: Chemical list: 2-aminopurine is misspelled.

d) Section D: Chemical list item # 7 need to include disposal methods for this chemical.

e) Section D; chemical list: 3,3'-Diaminobenzidine should probably be 3,3'-Diaminobenzidine and 2-aminopuine should probably be 2-Aminopurine.

f) Section E: Biological Safety Cabinet date of certification is incorrect.

g) Section B: 625A does not have a containment centrifuge.

**2. If you have any questions, please contact me at X65653.**

**7. McCormick, Paulette J., Ph.D.**

Education: ☐ Animal ☒ Human

## GI Gene Bank

ID: 00441 Prom#: N/A Protocol#: N/A

**STATUS:** Pending • **TYPE:** Human

(no approval)

**Protocol Dt: 06/05/2003**

**Other Reviews: IRB on 06/26/2003 [Approved]**

Co-Investigators [(\*)= on committee]: Pasquale(\*)

Initial Review

Approved ICF Versions: 07/24/2003

Sponsor: 9307 = State Government • Admin: 02 = VA

Sponsor: 9009 = VA - Other Designated Research • Admin: 02 = VA

Sponsor: 9399 = SUNY Albany • Admin: 02 = VA

Reviewers: Bove • Selden

THE FOLLOWING ITEMS WERE REVIEWED AT MEETING (\* = stipulations):

- Biosafety Information Form (06/19/2003; Disapproved)
- Dr. Pasquale response (07/10/2003)

Dr. Pasquale's update to committee on our off-site activities.

1. RPI- Dr. Dordick has resigned his VA appointment and Dr. Hogg is in the process of moving on site. Thus, we no longer have any off-site research at RPI. This makes biosafety issues there moot.

2. SUNY- Dr. McCormick is the only VA investigator at that site (all others no longer have VA appointments). The previously (a few years ago) R&D approved studies have expired (per our new SOP). Thus, currently there is no VA research being done at SUNY. The only activity anticipated at SUNY will be this gene bank project.

Thus, I did not move forward with the off-site biosafety committees. However, the gene bank was an oversight on my part. I agree in full with your determination and will move forward to obtain the appropriate documentation from SUNY.

- Note from P. Phillips to Dr. Pasquale (07/10/2003)

As Chair of the SRS&B Committee I have concerns about this Gene Bank protocol. The last time this issue was presented to the Committee you stated that there would be no issues for the Committee to deal with at the off-site laboratories. The SRS&B Information form states otherwise, as it contains a list of chemicals as well as procedures involving tissues and recombinant DNA procedures. The descriptions of recombinant DNA procedures and cell line development are particularly vague, and as such cannot be approved. In addition, as Pam Colligan has stated in her e-mail to you, there are a number of practical questions concerning the handling of chemicals that are important to resolve before approval is given.

The major issue is still this. We as a Committee support the concept that SUNY on-site Safety personnel are best situated to monitor the activities at that site. Lynn Selden provided you with names of Safety personnel contacts within the SUNY system who could provide such oversight. Before the proposal is approved by Committee we must have documentation about how these issues will be addressed.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Initial Review

Disapproved [For: 12 Against: 0 Abstained: 0 Recused: 0 Excused: 0]

Letter Dates - Disapproval: 07/15/2003

Letter Text:

[REDACTED]

- i. Page 3; Section C; Under Recombinant DNA: This section is particularly vague. What proteins will be expressed? Please give examples. What plasmid vector(s)? Which E. coli strains?
- j. Page 3; Section D; Under Chemical: It appears that a cut-and-paste approach was taken to this section without apparent awareness to the properties or hazards of individual chemicals.
- k. Page 3; Section D; Under Chemical: Where are the chemicals to be stored? Is it in room B233 at CFG? Or B233 at the VA? And if it isn't room B233 at CFG then where in CFG?
- l. Page 6; Section E; Under Containment: A BSL2 biological safety cabinet is required for this research. (I suspect that the existing cabinet is a BSL2, but the investigator should make sure that this is the case and so indicate. Note that the laboratory safety cabinet inspection will expire this month and a new inspection and date should be included on the next submission of this statement.
- m. Page 6; Section E; Under Containment Equipment: If blood will be centrifuged, it should be stated that containment of centrifuged samples would be insured during centrifugation. There are several ways this can be accomplished. The bottom line is that the investigator needs to make sure that if a tube leaks, the leak is contained so that effective and relatively easy decontamination can be accomplished.

Department of Environmental Health and Safety



Chemistry B73  
Albany, New York 12222

518/442-3495  
Fax: 518/442-3783

**UNIVERSITY AT ALBANY**  
STATE UNIVERSITY OF NEW YORK

July 14, 2003

Dr. Donald Pasquale  
Stratton VA Medical Center  
113 Holland Avenue  
Albany, New York 12208

Dear Dr. Pasquale:

[REDACTED]

The Environmental Health and Safety Office is familiar with the research activities of the CFG Labs, and is aware that collaborative studies proposed with the Stratton VA Medical Center will include the receipt and storage of human blood samples and the extraction of genomic DNA from such samples. Genetic tests to be performed on these DNA samples, such as genotyping and DNA sequence analysis, are already routinely performed in the CFG labs.

If you have any questions regarding this inspection, please feel free to contact me at 442-3495.

Sincerely,

[REDACTED]

Lisa-Anne B. Donohue, CIH, CSP, CHO  
Assistant Director of Environmental Health and Safety  
University at Albany, Chemistry B73

Cc: Dr. Paulette McCormick  
Dr. John Tine ✓  
Vincent Franconiere

Office of the Vice President for Research



University Administration Building  
Room 417  
Albany, New York 12222

518/437-4960  
Fax: 518/437-4962

**UNIVERSITY AT ALBANY**  
STATE UNIVERSITY OF NEW YORK

October 10, 2003

Mr. Arnold Johnson  
Chair, Research & Development Committee  
Stratton VA Medical Center  
113 Holland Avenue  
Albany, NY 12208

Dear Mr. Johnson:

The Institutional Biosafety Committee at the University at Albany, State University of New York, met on October 9, 2003, and discussed the safety and biosafety issues related to aspects of the GI Gene Bank being developed jointly with the Stratton VA and the University.

The University, through its Institutional Biosafety Committee (IBC), will take responsibility for the work on this project that takes place at the University's Center for Functional Genomics. [REDACTED]  
Ann Weatherwax, Ph.D. [REDACTED]  
[REDACTED]

Sincerely,

[REDACTED]  
Jeryl M. Mumpower  
Interim Vice President for Research

c: R. Cunningham  
J. Weatherwax

Old Business

[REDACTED]

8. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Open

9. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Open

10. Business Item carried forward from the 10/1/03 meeting.

Item: Update on Gene Bank Biosafety issues at SUNY@Albany

Discussion: SUNY will oversee all safety issues at the East Campus therefore Dr. McCormick's protocol is, exempt from VA SRS&B approval.

Closed

11. Business Item carried forward from the 10/1/03 meeting.



Old Business

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
Open

New Business

1. [REDACTED]  
[REDACTED]  
[REDACTED]

2. Biosafety Informational Form:

The subcommittee will discuss the need to revise the form to include NIH exemptions.

Discussion: The subcommittee recommended adding the following to the Biosafety Informational Form: (1) add (s) at the end of principal investigator, (2) add (s) to the end of co-investigator, (3) add Funding Source to form, (4) add Department Of Transportation training under Sections A & B, (5) a yes or no statement will be added: if materials will be mailed out under Sections A & B and (6) add under Section C number 7 the list of NIH exemptions.

A new item detailing requirements for exempt Recombinant DNA) was added under the Section C Recombinant DNA. All pending, active or in follow-up protocols were updated in the MIRB Database from Recombinant DNA to Exempt Recombinant DNA to reflect their exempt status as per NIH guidelines.

Responsibility: Drs. Pasquale & Phillips; Ms. McLaren  
Open

3. Donald K. Phillips resigned effective April 1, 2004.

Discussion: The subcommittee recommended that a letter be sent to NIH Headquarters with a current roster and request that at this time we be exempt from the recommended 2 community members. The subcommittee will look to replace our community members and to kept in compliance with NIH regulations. The subcommittee would like the necessary members in the event that a principal investigator submits Recombinant DNA research in the future. A letter of appreciation for serving on the subcommittee will be sent to Mr. Phillips. Mr. Birnby also resigned from the subcommittee effect June 15, 2004.

**EXPEDITED - Initial Review**

[REDACTED]

**EXPEDITED - Previously Tabled Protocol (Initial Review)**

1. McCormick, Paulette J., Ph.D. Education: ☐ Animal ☒ Human

GI Gene Bank

ID: 00441 Prom#: N/A Protocol#: N/A

Protocol Dt: 06/05/2003

STATUS: Pending • TYPE: Human

Approved 03/10/2004

No Biosafety Prev Tbl

Other Reviews: IRB 06/26/2003 [Contingent Approved; Final Approval 07/28/2003], R&D 04/16/2004

Co-Investigators [(\*) = on committee]: Pasquale, D. T.(\*)

Conflict of Interest: Pasquale, D. T.

Approved ICF Versions: 07/24/2003

Sponsor: 9307 = State Government • Admin: 02 = VA

Sponsor: 9009 = VA - Other Designated Research • Admin: 02 = VA

Sponsor: 9399 = SUNY Albany • Admin: 02 = VA

ITEMS REVIEWED (\* = stipulations):

- Abstract (06/05/2003)
- Biosafety Informational Form - Exempt (06/19/2003)
- Letter (02/04/2004)

Attached is a copy of the approved letter of agreement as it pertains to the "GI Gene Bank" and safety issues. Signatures have been obtained by the following: Paulette J. McCormick, Ph.D., Principal

**EXPEDITED - Previously Tabled Protocol (Initial Review)**

- Investigator, VAMC; Richard Cunningham, Ph.D., IBC Chair, SUNY@Albany; Arnold Johnson, Ph.D., R&D Chair, VAMC & Patricia G. Phillips, Ph.D., SRS&B Chair, VAMC

February 4, 2004

Jeryl L. Mumpower, Interim Vice President for Research  
University at Albany  
State University of New York  
University Administration Building Room 417  
Albany, New York 12222

Dear Mr. Mumpower:

The Subcommittee on Research Biosafety and Safety (SRS&B), met on January 14, 2004, and discussed your letter dated October 10, 2003 addressed to Mr. Johnson, Research & Development Chair. Please note for future correspondence, the correct title is Arnold Johnson, Ph.D.

The Subcommittee on Research Biosafety and Safety (SRS&B) concurs with your decision to have your Institutional Biosafety Committee (IBC) take responsibility for the safety and biosafety issues related to the following protocol entitled, "GI Gene Bank", at the University's Center for Functional Genomics.

**EXPEDITED - Continuing Review**

[REDACTED]

**EXPEDITED - Continuing Review**

2. Baltch, Aldona, M.D.

Education: ☒ Animal ☒ Human

Effects of Recombinant Activated Protein C (ACP) on Human Monocyte Activity and Modulation of Proinflammatory Cytokines in the Presence of Antimicrobial Agents (Expedited Review Category 2)

ID: 00410 Prom#: 0069 Protocol#: N/A

Protocol Dt: 02/04/2003

STATUS: Active • TYPE: Human

Approved 03/05/2004

Biosafety Init Approval Dt: 04/02/2003

Other Reviews: IRB 02/26/2004 [EXPEDITED Approval 01/14/2004], R&D 03/05/2004 [Approved]

Co-Investigators [(\*) = on committee]: Smith, R. P.(\*)

Research Coordinators [(\*) = on committee]: Bopp, L. A.

Research Staff [(\*) = on committee]: Ritz, W.(\*)

Approved ICF Versions: 12/03/2003

Sponsor: 9731 = Eli Lilly • Admin: 06 = Albany Research Institute

Reviewer: Phillips, P. G.

ITEMS REVIEWED (\* = stipulations):

- Biosafety Informational Form - #03-013 (3/21/03) (02/04/2003)
- SRS&B Questionnaire/Continuing Review - No change to Biosafety Informational Form (03/04/2004)

The SRS&B Chair reviewed and approved a one year continuation of the previously approved Biosafety Information Form.

[REDACTED]

4.

Other Reviews Completed: R&D (Just-In-Time) 03/05/2004 [Approved]

Other Reviews Scheduled: R&D 10/15/2004

Sponsor: 9003 = VA - Merit Review • Admin: 02 = VA

Reviewers: Smith, R. P. • Bove, K.

ITEMS REVIEWED (\* = stipulations):

- [REDACTED]
- [REDACTED]
- Recombinant DNA Form (09/02/2004)

ITEMS RECEIVED AFTER Contingent Approval:

- [REDACTED]

1. Section C: Under Recombinant DNA: Please indicate what human tissues/cells the DNA is coming from.
2. Section C: Under Recombinant DNA: Is cofilin the only DNA to be expressed?
3. Section C: Under Recombinant DNA: How will the PI obtain the gelsolin and the profilin?
4. Reviewer's Critique: Under Abstract: The abstract submitted with this Biosafety form does not address the use of human blood, nor does it indicate the plans for using the rDNA. Without knowing this it is hard to determine if the form has been filled out completely.

YES

5.

Other Reviews Completed: R&D (Just-In-Time) 02/20/2004 [Approved], R&D (Final Approval) 08/20/2004 [Tabled], R&D (Final Approval) 09/10/2004 [Approved; Final Approval 09/22/2004]  
Sponsor: 9209 = Department of Health and Human Services • Admin: 06 = Albany Research Institute  
ITEMS REVIEWED (\* = stipulations):

1) Under Section A. Human Tissue Samples: Item # 3: Please complete this section, including human cell lines to be used.

4) Under Section C: Recombinant DNA: Item # 5: Cell/animal/plant recipient(s): rat and mouse endothelium are listed. Will human cell lines (as indicated in the abstract) also be used?

All contingencies were reviewed and approved by the SRS&B Chair or designee.

Approved: [For: 7 Against: 0 Abstained: 0 Recused: 1 (Dr. Johnson) Excused: 0]

**EXPEDITED - Initial Review**

- \* Biosafety Informational Form - Draft (06/30/2004)
- Approval for Use of Radioactive Materials (12/06/2000; Expires 8/3/05)
- Recombinant DNA Form (06/30/2004)

**ITEMS RECEIVED AFTER Contingent Approval:**

- Biosafety Informational Form - Final (07/25/2004; #04-16 (7/29/04))

- 1) A. Under Human Tissue Samples: Item # 3: Please complete BSL.
- 2) D. Under Chemicals: Section E: Please fill out Biosafety Cabinet information. Resveratrol should be on the Chemical List.
- 3) D. Under Chemicals: Section Chemical List: Ethidium bromide needs to be detoxified using a special filter prior to disposal.

Reviewer's Critique: I'm not familiar with these particular cells but if they are established lines I'm not sure what exactly the hazard risk would be. If the investigators are aware of pathogens that are present in these particular cell lines then that needs to be stated and the appropriate Biosafety level for those pathogens should be assigned as well as the specific precautions for that Biosafety level.

All contingencies were reviewed and approved by the SRS&B Chair or designee.

Approved: [For: 7 Against: 0 Abstained: 1 (Dr. Bove) Recused: 0 Excused: 0]

1







**EXPEDITED - Continuing Review**

1. **Cunningham, Richard, Ph.D.**

GI Gene Bank

Education Requirement Met? ☒

ID: 00441 Prom#: 0003 Protocol#: N/A

Protocol Dt: 06/05/2003

STATUS: Active • TYPE: Human

Approved 03/17/2006

Biosafety Init Approval Dt: 03/10/2004

Other Reviews Completed: IRB 05/26/2005 [EXPEDITED Approval 05/10/2005], R&D 04/15/2005 [Approved]

Other Reviews Scheduled: IRB 04/27/2006, R&D 04/21/2006

Co-Investigators [(\*) = on committee]: Pasquale, D. T.

Approved ICF Versions: 04/12/2005, 04/21/2004, 07/24/2003

Sponsor: State Government (9307) • Admin: VA (02)

Sponsor: VA - Other Designated Research (9009) • Admin: VA (02)

Sponsor: SUNY Albany (9399) • Admin: VA (02)

Reviewer: Chu, R. C.

ITEMS REVIEWED (\* = stipulations):

- Biosafety Informational Form - Exempt (06/19/2003)
- Project Data Sheet - (Biosafety) (02/15/2006)
- SRS&B Questionnaire/Continuing Review (02/12/2006)

[REDACTED]

[REDACTED]