

Interoffice Memorandum



August 24, 2009

McLean Hospital

155 South Street, Belmont, MA 02478-0106

Dr. Jack Bergman

(b)(6)
Alcohol and Drug Abuse Center
McLean Hospital
Belmont, MA 02478

Re. Space radiation studies

Dear Drs. Bergman

(b)(6)

Your letter dated July 30, 2009 responding to the committee's questions regarding your addendum request to study the long-term neurobehavioral and neuropharmacological effects of exposure to radiation (Fe56 and protons) in squirrel monkeys was reviewed and approved by the McLean Hospital IACUC at its meeting on August 12, 2009. Your addendum now has final approval.

Title of Application: Preclinical Pharmacology of CNS Drugs: Master Protocol
Title of Subproject: Long-Term Effects of Space Radiation in Nonhuman Primates
Principal Investigator: Dr. Jack Bergman

Name of Institution: McLean Hospital
IACUC Approval No.: 09-5/2-18
IACUC Approval Date: August 12, 2009

(b)(6)

McLean Hospital has a PHS-approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). The Assurance number is A3685-01.

Sincerely,

(b)(6)

(b)(6)

McLean Hospital

115 Mill Street, Belmont, Massachusetts 02478-9106
Telephone 617 855-2000, FAX 617 855-3299



January 13, 2010

(b)(6) Dr. Jack Bergman, Principal Investigator

Preclinical Pharmacology Program
Mailman Research Center
McLean Hospital
Belmont, MA 02478

Title of the Application: Preclinical pharmacology of CNS drugs:
Master Protocol #09-5/2-18

Title of Subproject: Ground-Based Studies in Neurobehavioral Biology

Dear Dr. Bergman:

(b)(4)
The IACUC committee reviewed and approved your response at it's meeting of January 13, 2010 and your addendum now has final approval.

This institution has an Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). The Assurance number is A3685-01.

Sincerely,

(b)(6)

(b)(6)

(b)(6)

non-response

----- Forwarded Message

From: Jack Bergman

Date: Tue, 17 Nov 2009 12:04:35 -0600

To: Stephen Davison <stephen.c.davison@nasa.gov>, (b)(6)

Cc: Francis Cucinotta <francis.a.cucinotta@nasa.gov>

Subject: RE: McLean Hospital Animal Care Facility (b)(6)

Hi Steve,

The McLean Hospital Animal Care Facility and the NERPRC facility are separate and independent facilities, though both NERPRC and McLean have relationship to Harvard Medical School. NERPRC is part of the Medical School, whereas McLean Hospital is affiliated with the Medical School. and I are both faculty at Harvard Medical School.) (b)(6)

Regarding documentation on the McLean Facility's certification, I will check with the facility manager and get back to you.

Best,

Jack

Jack Bergman, Ph.D.
McLean Hospital

(b)(6)

-----Original Message-----

From: Davison, Stephen C. (HQ-BL000)

[mailto:stephen.c.davison@nasa.gov]

Sent: Tuesday, November 17, 2009 9:59 AM

To: Bergman, Jack

Cc: Cucinotta, Francis A. (JSC-SK311)

Subject: McLean Hospital Animal Care Facility

Dr. Bergman:

Two quick questions:

1. What is the relationship between NIH/NEPRC and the McLean Hospital Animal Care Facility?
2. Is there any documentation that can be provided on the McLean Hospital Animal Care Facility's formal certifications?

Steve

--
Steve Davison

Advanced Capabilities Division

Exploration Systems Mission Directorate

NASA Headquarters
Washington, DC 20546

Office: 202-358-0647

Email: stephen.c.davison@nasa.gov (b)(6)

----- End of Forwarded Message

non-Response

----- Forwarded Message

From: Jack Bergman . (b)(6)

Date: Wed, 18 Nov 2009 13:49:33 -0600

To: Stephen Davison <stephen.c.davison@nasa.gov>

Cc:

Subject: RE: McLean Hospital Animal Care Facility (b)(6)

Hi Steve,

Just to follow up further on your query re: certification of our animal facility. McLean Hospital has a PHS-approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). The assurance number is A3685-01. (FYI, that information is in the IACUC approval letter that accompanies the original proposal.) In addition, if it helpful, our hospital IACUC reviews our protocols regularly (current approval # is 09-5/2-18). We hope this is helpful. Let us know if you need further

information.

Best,

Jack

Jack Bergman, Ph.D.
McLean Hospital

(b)(6)

-----Original Message-----

From: Davison, Stephen C. (HQ-BL000)
[mailto:stephen.c.davison@nasa.gov]
Sent: Tuesday, November 17, 2009 9:59 AM
To: Bergman, Jack
Cc: Cucinotta, Francis A. (JSC-SK311)
Subject: McLean Hospital Animal Care Facility

Dr. Bergman:

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1. What is the relationship between NIH/NEPRC and the McLean Hospital Animal Care Facility?
2. Is there any documentation that can be provided on the McLean Hospital Animal Care Facility's formal certifications?

Steve

--
Steve Davison
Advanced Capabilities Division
Exploration Systems Mission Directorate
NASA Headquarters
Washington, DC 20546

Office: 202-358-0647

(b)(6)
Email: stephen.c.davison@nasa.gov

----- End of Forwarded Message

National Aeronautics and
Space Administration

Lyndon B. Johnson Space Center
2101 NASA Parkway
Houston, Texas 77058-2896



October 14, 2009

SK-09-278

Dr. Jack Bergman
The Melean Hospital Corporation

(b)(6)

Dear Dr. Bergman:

This is not an authorization to proceed with your project, and you should be aware that NASA may not reimburse any expenditure of funds incurred before satisfactory technical and contractual arrangements are agreed upon. All awards concerning this investigation will be to your institution. You and your institution will be held responsible by NASA for carrying out the investigation. These responsibilities are described in the NRA and will be established in more detail in the subsequent award. Funding for this award will begin no earlier than November 1, 2009, contingent on availability of funds as appropriated by the Congress. Costs should not be incurred on this project prior to authorization by the NASA Grants Officer.

I wish to extend my personal appreciation to you for your interest in the NASA Human Research Program and the NASA mission. I congratulate you on the success of your proposal in this highly competitive forum.

Sincerely,

A handwritten signature in cursive script that reads "Dennis J. Granda".

Dennis J. Granda
Manager, Human Research Program
Exploration Systems Mission Directorate

SK-09-278

2

cc:

SK/F. A. Cucinotta

SK/S. W. Krenk

SK/F. M. Sulzman

HQ/Advance Capabilities, Human Systems Research and Technology B. Neumann

NRESS-K. Willison

Office of Research Administration

BROOKHAVEN
NATIONAL LABORATORY

Building 410
P.O. Box 5000
Upton, NY 11973-5000

(b)(6)

managed by Brookhaven Science Associates
for the U.S. Department of Energy

Memo

(b)(4)

Cucinotta, Francis A. (JSC-SK311)

From: Jack Bergman (b)(6)
Sent: Thursday, June 25, 2009 4:54 PM
To: (b)(6)
Cc: Cucinotta, Francis A. (JSC-SK211)

Dear Mr. Willison,

I am writing to ask your help. I, (b)(6) and my administrative assistant at McLean Hospital have been trying to submit our Step 2 proposal to NASA (09-Rad09Step2-0060) by the deadline of 5:00 p.m. today. As you know from phone conversations, we had considerable technical difficulties that prevented us from meeting the deadline time precisely. I understand that deadlines are set up for a reason but, in this case, the technical difficulties were not of our doing. Despite consulting the HELP line, we were unable to get a properly formatted document transmitted to NSPIRES in time. After we finally did get a properly formatted document that went through to NSPIRES successfully, I received an e-mail notification from NSPIRES that the proposal was received at 5:04 p.m. and, subsequently, another e-mail notice that it was late. As you can imagine, that has caused us considerable consternation, especially in light of our struggles to get this proposal submitted in time despite the technical issues that we faced. I am hopeful that you may be able to help us out to insure that our proposal moves forward properly rather than being treated as a late proposal.

I understand that there may be some concern regarding extra time (at this point, 53 minutes) that may be advantageous for the late submission. As the principal investigator, I can pledge to you that the proposal was completed well before the deadline time and has not been changed since. I am attaching a .pdf copy of the proposal in the event you wish to compare it to the document that was submitted through NSPIRES.

I hope that you are able to help us in this matter. Thank you in advance for your kind consideration of our request.

Sincerely yours,

Jack Bergman, Ph.D.

Jack Bergman, Ph.D.
McLean Hospital

(b)(6)

Cucinotta, Francis A. (JSC-SK311)

From: Cucinotta, Francis A. (JSC-SK211)
Sent: Thursday, September 03, 2009 3:59 PM
To: 'Jack Bergman'
Cc: (b)(6)
Subject: RE: Nasa Space Radiation Proposal

Hi Jack:

This week we had our formal meeting on the selection of Space Radiobiology proposals. Congratulations and we look forward to working with you. Formal letters will be sent in about a week.

As we briefed our management, one topic came up is to be prepared for any public relations issues that could arise with upper NASA management or the public. NASA has funded primate research in the past but not in the last few years.

We will be preparing a set of RTQ or FAQ's for NASA's Public affairs office and were hoping we could discuss these with you next Tuesday. This should only take about 30 minutes so if you let us know a good time - preferably in the morning that would be a big help.

Best regards,

Francis

Cucinotta, Francis A. (JSC-SK311)

From: Bergman, Jack (b)(6)
Sent: Friday, September 04, 2009 9:49 AM
To: Cucinotta, Francis A. (JSC-SK211)
Cc: (b)(6)
Subject: RE: Nasa Space Radiation Proposal

Hi Francis,

Thank you. We are looking forward to a very fruitful relationship with you and NASA. I am optimistic that our project will be highly successful, and provide a meaningful boost (pun intended!) to the agency's programs.

Regarding teleconference, I am certainly available Tuesday morning at your convenience. Just let me know what time is good for you.

Best regards,

Jack

Jack Bergman, Ph.D.

(b)(6)

From: Cucinotta, Francis A. (JSC-SK211) [francis.a.cucinotta@nasa.gov]
Sent: Thursday, September 03, 2009 4:59 PM
To: Bergman, Jack
Cc: (b)(6)
Subject: RE: Nasa Space Radiation Proposal

Hi Jack:

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Best regards,

Francis

Cucinotta, Francis A. (JSC-SK311)

From: Cucinotta, Francis A. (JSC-SK211)
Sent: Friday, September 04, 2009 12:25 PM
To: Bergman, Jack
Cc: (b)(6)
Subject: RE: Nasa Space Radiation Proposal

Hi Jack:

Thanks.

I will call you at 11 AM central on Tuesday.

-Francis

-----Original Message-----

From: Bergman, Jack (b)(6)
Sent: Friday, September 04, 2009 9:49 AM
To: Cucinotta, Francis A. (JSC-SK211)
Cc: (b)(6)
Subject: RE: Nasa Space Radiation Proposal

Hi Francis,

Thank you. We are looking forward to a very fruitful relationship with you and NASA. I am optimistic that our project will be highly successful, and provide a meaningful boost (pun intended!) to the agency's programs.

Regarding teleconference, I am certainly available Tuesday morning at your convenience. Just let me know what time is good for you.

Best regards,

Jack

Jack Bergman, Ph.D.
McLean Hospital / Harvard Medical School

(b)(6)

From: Cucinotta, Francis A. (JSC-SK211) [francis.a.cucinotta@nasa.gov]
Sent: Thursday, September 03, 2009 4:59 PM
To: Bergman, Jack
Cc: (b)(6)
Subject: RE: Nasa Space Radiation Proposal

Hi Jack:

This week we had our formal meeting on the selection of Space Radiobiology proposals. Congratulations and we look forward to working with you. Formal letters will be sent in about a week.

As we briefed our management, one topic came up is to be prepared for any public relations issues that could arise with upper NASA management or the public. NASA has funded primate research in the past but not in the last few years.

We will be preparing a set of RTQ or FAQ's for NASA's Public affairs office and were hoping we could discuss these with you next Tuesday. This should only take about 30 minutes so if you let us know a good time - preferably in the morning that would be a big help.

Best regards,

Francis

Cucinotta, Francis A. (JSC-SK311)

From: Cucinotta, Francis A. (JSC-SK311)
Sent: Friday, October 23, 2009 12:10 PM
To: (b)(6)
Cc:
Subject: Re: Nasa Space Radiation Proposal

Hi Jack

Just in case you had not received the material- Leah at BNL can send you all of the forms for the Beam time proposal for the NSRL experiments.

The proposals are evaluated 3 times a year. The next deadline is approaching soon (Nov 5), but since its a new proposal we can allow a few days extension if needed.

-Francis

Cucinotta, Francis A. (JSC-SK311)

From: Jack Bergman (b)(6)
Sent: Friday, October 23, 2009 3:00 PM
To: Cucinotta, Francis A. (JSC-SK311)
Cc: (b)(6)
Subject: RE: Nasa Space Radiation Proposal

Thank you, Francis. I got the material from Leah and we will get on it ASAP.
Have an enjoyable weekend.

Best,

Jack

--you'll be amused to know that I am listening to the ongoing congressional discussions re:
NASA's future program with a wholly new perspective...

Jack Bergman, Ph.D.
McLean Hospital

(b)(6)

-----Original Message-----

From: Cucinotta, Francis A. (JSC-SK311)
[mailto:francis.a.cucinotta@nasa.gov]
Sent: Friday, October 23, 2009 1:10 PM
To: Bergman, Jack
Cc: (b)(6)
Subject: Re: Nasa Space Radiation Proposal

Hi Jack

Just in case you had not received the material- Leah at BNL can send you all of the forms
for the Beam time proposal for the NSRL experiments.

The proposals are evaluated 3 times a year. The next deadline is approaching soon (Nov 5),
but since its a new proposal we can allow a few days extension if needed.

-Francis

Cucinotta, Francis A. (JSC-SK311)

From: Jack Bergman (b)(6)
Sent: Thursday, November 12, 2009 5:19 PM
To: Cucinotta, Francis A. (JSC-SK311)
Cc: (b)(6)
Subject: RE: e-mailed questions to Dr. Bergman

Hi Francis,

Weil, that doesn't sound altogether encouraging. For what it's worth, I don't think NIH will provide any negative surprises. First, the NIH itself supports regional primate centers! Second, the agencies (e.g., NIMH or NIDA) depend on study sections for review of applications for scientific worth (which includes concerns regarding appropriate use of animals) and on home institutional animal review committees (IACUCs), as we described in the phone conference.

Should we be concerned that this work ultimately will not be funded? If so, should we hold off setting up for this project? If we can help further in any way, please let us know.

Best,

Jack

Jack Bergman, Ph.D.
McLean Hospital

(b)(6)

-----Original Message-----

From: Cucinotta, Francis A. (JSC-SK311) [mailto:francis.a.cucinotta@nasa.gov]
Sent: Thursday, November 12, 2009 5:23 PM
To: Bergman, Jack
Cc: (b)(6)
Subject: Re: e-mailed questions to Dr. Bergman

Hi Jack

Thanks very much for helping out.

Don't know for sure but believe it will be a mixed outcome. The management is more convinced than before on need for this research. However want to look at how NIH or other agencies reviews non-human primate research as a check.

Nasa does human research (for example bed-rest studies) and animal studies. I guess I am not sure where this look and see will lead.

-Francis

Non-Response

NON-RESPONSIVE

NON-RESPONSIVE

Cucinotta, Francis A. (JSC-SK311)

From: Bergman, Jack (b)(6)
Sent: Friday, November 13, 2009 6:09 AM
To: Cucinotta, Francis A. (JSC-SK311)
Cc: (b)(6)
Subject: RE: e-mailed questions to Dr. Bergman

Thanks, Francis. That helped me sleep better. If we don't speak today, have an enjoyable weekend!

Best,

Jack

Jack Bergman, Ph.D.
McLean Hospital / Harvard Medical School

(b)(6)

From: Cucinotta, Francis A. (JSC-SK311) [francis.a.cucinotta@nasa.gov]
Sent: Thursday, November 12, 2009 6:30 PM
To: Bergman, Jack
Cc: (b)(6)
Subject: Re: e-mailed questions to Dr. Bergman

Hi Jack

I very confident come January funding will be provided and study proceed as planed.

But in the mean time some folks at NASA Hq will find out what your message reports- their is no other review steps beyond the ones we have followed used by other agencies. By the way the peer review panel raised no issues in reviewing your proposal and they typically are quite vocal if they had an issue.

I think finalizing the revised SOW is still next step, but will of course let you know if another one is asked for.

Best regards,

Francis

From: Jack Bergman (b)(6)
To: Cucinotta, Francis A. (JSC-SK311)
Cc: (b)(6)
Sent: Thu Nov 12 17:18:33 2009
Subject: RE: e-mailed questions to Dr. Bergman

Hi Francis,

Well, that doesn't sound altogether encouraging. For what it's worth, I don't think NIH will provide any negative surprises. First, the NIH itself supports regional primate centers! Second, the agencies (e.g., NIMH or NIDA) depend on study sections for review of applications for scientific worth (which includes concerns regarding appropriate use of animals) and on home institutional animal review committees (IACUCs), as we described in the phone conference.

Should we be concerned that this work ultimately will not be funded? If so, should we hold off setting up for this project? If we can help further in any way, please let us know.

Best,

Jack

Jack Bergman, Ph.D.
McLean Hospital

(b)(6)

-----Original Message-----

From: Cucinotta, Francis A. (JSC-SK311) [mailto:francis.a.cucinotta@nasa.gov]

Sent: Thursday, November 12, 2009 5:23 PM

To: Bergman, Jack

Cc:

(b)(6)

Subject: Re: e-mailed questions to Dr. Bergman

Hi Jack

Thanks very much for helping out.

Don't know for sure but believe it will be a mixed outcome. The management is more convinced than before on need for this research. However want to look at how NIH or other agencies reviews non-human primate research as a check.

Nasa does human research (for example bed-rest studies) and animal studies. I guess I am not sure where this look and see will lead.

-Francis

-NON-RESPONSE

non-responsive

- non-responsive

Cucinotta, Francis A. (JSC-SK311)

From: Cucinotta, Francis A. (JSC-SK311)
Sent: Friday, November 20, 2009 9:22 AM
To: 'Jack Bergman'; (b)(6)
Subject: Update of IACUC

Hi Jack and (b)(6)

In case we forgot to ask- based on changes including additional controls -please send us a new IACUC approval from McLean as needed.

Thanks

Francis

Krenek, Sam (JSC-SK211)

From: Krenek, Sam (JSC-SK211)
Sent: Wednesday, December 02, 2009 11:16 AM
To: Cucinotta, Francis A. (JSC-SK311)
Cc: (b)(6); Sulzman, Frank M. (JSC-SK)
Subject: RE: heads up on an Added process

Jack – know that you have HUGE NASA support as well – from the project, to the program, to HQ..... But being NASA, HQ wants to proceed as cautiously and politically correct as possible – comes with the territory of a federal agency. So know that we're doing everything we can to get the award out to you (especially Francis).

sk

From: jbergman@hms.harvard.edu (b)(6)
Sent: Wednesday, December 02, 2009 11:07 AM
To: Cucinotta, Francis A. (JSC-SK311)
Cc: (b)(6); Krenek, Sam (JSC-SK211); Sulzman, Frank M. (JSC-SK)
Subject: Re: heads up on an Added process

Hi Francis,

We haven't heard from you, so I presume the telecon will go on w/out us or at another time. Let us know when and/or how to help. This primate issue is annoying but we are fully committed to the concept and work of the project. I don't understand how folks expect space research to progress otherwise. Regarding the issue of study length and euthanasia, I think it is important to stress that none of our work is terminal. The subjects we will use will live out their natural lives and be available to NASA for further study, should that be desired. Indeed, that is a notable strength of the project design.

Best,

Jack

Sent from my Verizon Wireless BlackBerry

(b)(4)

(b)(4)