



**Millennium Pharmaceuticals, Inc.**

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Cambridge, Massachusetts 02139  
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November 1, 2006

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

Re: Information Request – IBC Meeting Minutes (2004 and 2005)

Dear Dr. Hammond:

Pursuant to your request for information, enclosed are the minutes from the 2004 and 2005 IBC meetings at Millennium Pharmaceuticals, Inc. This request is being provided to you because the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules, Section IV-B-2-(7) states that upon request the institution shall make available to the public all Institutional Biosafety Committee meeting minutes.

Please note that Millennium Pharmaceuticals, Inc. had previously sent IBC meeting minutes for 2002 and 2003 in response to the Sunshine Project's 2004 survey of IBC's per letter sent February 17, 2004.

Lastly; I have enclosed a copy of a letter sent to the NIH stating my position as Biosafety Officer for Millennium Pharmaceuticals, Inc. Please direct all future correspondence to my attention at the address listed below.

Sincerely,

A handwritten signature in black ink that reads 'Cathy Guise'.

Cathy Guise  
Biosafety Officer  
Director EH&S  
Millennium Pharmaceuticals, Inc.  
40 Landsdowne Street  
Cambridge, MA 02139

Enclosures:

IBC Meeting Minutes 2004  
IBC Meeting Minutes 2005  
Letter to NIH – Updating BSO Position

**Millennium Pharmaceuticals, Inc.**

**IBC Committee Meeting September 23, 2004**

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## **Meeting Minutes - Final**

**Building 35 Landsdowne Street**

**Conference Room 35-3B**

Meeting began 5:00 p.m.

**Meeting attendees:** Hilary McNulty; Darshan Sappal; Mike Kuranda, Ph.D.; Petter Veiby, Ph.D. ; Benjamin Knight, M.S.

**Absent from Meeting:** Jay Morgenstern, Ph.D.; Diane Smith; Mary French; and Howard Lefkin, MS, CSP

### **1. Introductions of members**

Mike Kuranda, Ph.D. and Petter Veiby, Ph.D.

Gave a quick update on the purpose of the IBC, to review recombinant projects and that it is overseen by the NIH and Cambridge Biosafety Committee. I also reminded people that we had agreed to meet with earlier in the year to avoid the holiday scheduling issues during November and December.

Gave a quick update of Millennium's review process since we only meet once per year. When I get a new project, I review it and determine in which BSL it should be placed. If there are any questions I put it very conservatively in BL2+ until we get an opportunity to meet as a group and review it more completely.

### **2. Reshaping review – IBC projects**

IBC projects – 17 current projects

### **3. Discussion of Information Request by Sunshine Project – Described my understanding of what the Sunshine Project is doing regarding IBC and information requests. Let them review a copy of letter I sent to them. Lesson learned is where I have people's resumes with their personal information, I remove home address/phone and just submit experience and work information.**

### **4. Brought in minutes and asked Darshan if he had already signed a form approving the minutes from 2003. He said he did. The other people attending the meeting were not at the 2003 meeting.**

Meeting adjourned 5:30 p.m.

**Millennium Institutional Biosafety Committee (I.B.C.) Meeting Minutes  
November 11, 2005  
Location: Building 40 Landsdowne Street, Conference Room 5062**

**I.B.C. meeting convened at: 6:00 p.m.**

**Members Present:** Cathy Guise, Jay Morgenstern, Mike Kuranda, Benjamin Knight, Mary French, Howard Lefkin

**Members Absent:** Diane Smith, Petter Veiby, Darshan Sapple

**Minutes**

**1. I.B.C Membership: Cathy Guise**

Hilary McNulty no longer employed at Millennium as of November 11, 2005. Cathy Guise will be the chair of the I.B.C and will assume the role of Biosafety Officer for Millennium.

**2. Review of Protocols: Cathy Guise and Jay Morgenstern**

- **Project # 53 Pilot Scale Facility for Process Development-Cathy Guise:** The goal of this project is to test cell culture process changes using a 100 liter unit to generate material for downstream evaluation. The organisms that will be used are of mammalian origins and will not exceed BL1. The host cell line will be Chinese Hamster Ovary.

**Approved at BL1.** Note: Hilary documented that the committee approved the protocol at BL1 prior to the presentation to the Cambridge Biosafety Committee(CBC). The CBC approved the space plan and the protocol as well.

- **Project #51 Monoclonal Antibody Production (Bench Scale Work)-Cathy Guise:** The project goal is to generate hybridoma cell lines that produce monoclonal antibodies reactive with project targets for use as biomarkers, biotherapeutics or as reagents in assays.

**Approved at BL2**

- **Project # 50 Lentiviral shRNA (Bench Scale Work)-Jay Morgenstern:**The goal of this project is to obtain reagents from Sigma and assess how efficacious they are in knocking down expression levels of Millennium target genes in functional validation experiments. Specifically the reagents are virus generated from recombinant lentiviral vector.

**Approved at BL2+**

**Question:** Howard Lefkin asked for clarification on the NIH guidelines involving Principal Investigators (PI) reviewing their own project. I contacted Sam Lipson from the CBC and asked for his interpretation. The PI's can participate in the review of the project by the IBC. In fact it can be essential that the PI is available to provide necessary information to the committee members during the review. The PI can not vote on the approval of the protocol and Jay Morgenstern was excluded from voting on protocol #50.

**The Committee adjourned at 7 p.m.**



November 30, 2005

Michelle Johnson-Lancaster  
National Institutes of Health  
Office of Biotechnology Activities  
6705 Rockledge Drive, Suite 750  
MSC 7985  
Bethesda, MD 20892-7985

**RE: Millennium Pharmaceuticals' IBC Annual Report 2004**

Dear Michelle:

This letter is to inform you that Millennium Pharmaceuticals, Inc. conducted its annual Institutional BioSafety Committee (I.B.C.) meeting on November 11, 2005. The agenda and roster for this meeting is enclosed. As Hilary McNulty is no longer employed at Millennium, I will assume the role of BioSafety Officer and will be the Chair of the I.B.C.; a copy of my resume is attached.

If you have any questions or need addition information, please do not hesitate to contact me.

Regards,

A handwritten signature in cursive script that reads 'Cathy C. Guise'.

Cathy C. Guise, M.P.H.  
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Enclosures