



OFFICE OF THE CHANCELLOR

May 20, 2008

The Honorable Thomas V. Mike Miller, Jr.  
Co-Chair, Legislative Policy Committee  
State House  
Annapolis, MD 21401-1991

The Honorable Michael E. Busch  
Co-Chair, Legislative Policy Committee  
State House  
Annapolis, MD 21401-1991

Dear Chairmen:

In accordance with State Government Article Sections 15-523c concerning the quarterly and annual reporting requirements, I am providing you our quarterly report. During the quarter ending March 31, 2008, exemptions were granted by the University of Maryland, Baltimore, and the University of Maryland Center for Environmental Science, as indicated by the enclosed supporting documentation.

These exemptions are in accord with the Board of Regents' Policy on Conflicts of Interest in Research or Development and procedures developed in accordance with the provisions of the Public/Private Partnership Act.

Sincerely yours,

William E. Kirwan  
Chancellor

Enclosures

cc: The Honorable Martin O'Malley  
Members of the Legislative Policy Committee  
Members of the State Ethics Commission  
Office of the Attorney General

1807  
University of Maryland,  
Baltimore

1856  
University of Maryland,  
College Park

1865  
Bowie State University

1866  
Towson University

1886  
University of Maryland  
Eastern Shore

1908  
Burg State University

1900  
Coppin State University

1925  
Salisbury University

1925  
University of Baltimore

1925  
University of Maryland  
Center for Environmental  
Science

1947  
University of Maryland  
University College

1966  
University of Maryland,  
Baltimore County

1985  
University of Maryland  
Biotechnology Institute

21767-30001





**UNIVERSITY OF MARYLAND**

Office of the President

**DAVID J. RAMSAY, DM, DPhil**  
President

520 West Lombard Street  
Baltimore, Maryland 21201-1627  
410 706 7002 | 410 706 0500 FAX

**RECEIVED**

APR 16 2008

**MEMORANDUM**

**TO:** William E. Kirwan, Ph.D.  
Chancellor

**FROM:** David J. Ramsay, D.M., D.Phil.  
President, University of Maryland, Baltimore

**DATE:** April 14, 2008

**RE:** Third Quarter Report on Exemptions Granted Pursuant  
To the Public-Private Partnership Act

CHANCELLOR'S OFFICE

There were two (4) exemptions granted to UMB personnel between January 1, 2008 and March 31, 2008, pursuant to the Public-Private Partnership Act.

Supporting documentation is enclosed.

EMPLOYEE	INTEREST	ENTITY	DATE OF EXEMPTION
Anthony DeVico, Ph.D.	Equity, Inventor	Profectus Biosciences, Inc.	1/22/2008
Robert Gallo, M.D.	Equity, Inventor, Consultant	Profectus Biosciences, Inc.	1/22/2008
George Lewis, Ph.D.	Equity, Inventor	Profectus Biosciences, Inc.	1/22/2008
Stephen Gottlieb, M.D.	Consultant	Biogen Idec	3/24/2008

If any further information is required, please do not hesitate to contact Mr. Joe Giffels in the Office of the Vice President of Academic Affairs at (410) 706-1853.

**PC:** Mr. Joe Giffels  
Dr. Malinda Orlin  
State Ethics Commission





**UNIVERSITY OF MARYLAND**


Office of the President

**DAVID J. RAMSAY, DM, DPhil**  
President

520 West Lombard Street  
Baltimore, Maryland 21201-1627  
410 706 7002 | 410 706 0500 FAX

**MEMORANDUM**

**TO:** Anthony DeVico, Ph.D.  
Professor of Medicine  
School of Medicine

**FROM:** David J. Ramsay, D.M., D.Phil.  
President 

**DATE:** January 22, 2008

**SUBJECT:** Conflict of Interest Disclosure #01-08-002

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated June 29, 2007. Your request involves proposed relationships between you and Profectus Biosciences, Inc. (Profectus). You propose uncompensated service on Profectus’s Scientific Advisory Board and ownership of equity in Profectus. In addition, Profectus is anticipated to license technologies invented by you and which are owned by the University of Maryland Baltimore (UMB). As an inventor you stand to receive a share of institutional royalties as a result of the licenses of your inventions. As a shareholder of Profectus, you stand to benefit from the license of the inventions of your colleagues.

These proposed relationships present a conflict of interest because you plan to participate as a UMB investigator on research of interest to, and possibly supported by, Profectus.

I find that your association with Profectus will facilitate research and development. I have determined that your relationship with Profectus would not be a harmful interest, as described in the USM Board of Regents’ Policy on Conflicts of Interest in Research and Development, provided you comply with the conditions set out in this Exemption. This Exemption permits your association with Profectus as described in your exemption request, with the exceptions listed below. This Exemption is valid from the date of this memorandum through January 22, 2009. Further extension of this Exemption, with or without revision, will be considered, but not guaranteed, for the period beginning January 23, 2009.

In the absence of this Exemption, or in the event you do not comply with the conditions set out in this Exemption, your association with Profectus will conflict with the Maryland Public Ethics Law, as well as University System of Maryland and UMB policy, rendering

you subject to disciplinary action and other penalties allowed by State law and UMB and USM policy.

The conditions of this Exemption follow:

- All of your business and financial relationships with Profectus must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and research subjects) participating in your research, and to sponsors of your research. The requirement will apply whether or not Profectus is a research sponsor, and whether or not it is directly involved in the research. Your relationships with Profectus must also be disclosed whenever you publish or speak about the research, including during informal presentations made on or off campus, such as departmental seminars. Disclosure shall include enough detail of the business aspects of your Profectus relationships to enable an understanding of the significance of the relevant financial relationships. The statement of disclosure must be approved by the campus conflict of interest officer. UMB will review the disclosure annually and you will modify it as required given any changes in your relationships to Profectus. This Exemption shall be posted to UMB's public web site, shall be placed on file in the Health Sciences and Human Services Library, and will be in the public records of the State Ethics Commission.
- You cannot be the principal investigator for research involving human subjects where that research is of interest to Profectus. A principal investigator, a qualified scientist, must be identified who is not in the IHV and who does not have a similar financial interest related to the research. Your agreement to adhere to this plan must be clearly documented prior to the initiation of the study and must be part of the IRB proposal.
- On a quarterly basis, you must submit detailed reports on research plans, progress and publications. The reports must include all research in which you are involved and must be submitted to the Dean or his designee for evaluation, with a copy to the UMB Conflict of Interest Officer. Research notebooks must be maintained according to Good Laboratory Practices, including the requirement that all pages of notebooks be signed by the person conducting the experiment and a witness or reviewer who can objectively review the information, but who is not integrally involved in the collection of the data. At all times, all research records (including notebooks, computers, data, etc) must be available for inspection by the Dean's designee and UMB officials and research lab meetings shall be open to these same individuals.
- At least annually, the Dean's designee will schedule a meeting with you to discuss the research and conflict of interest issues to ensure the integrity of the research. The Dean's designee may enlist the expertise of other UMB scientists, or consultants to UMB, as necessary to evaluate the research and financial interests. These discussions will be documented in writing by the Dean's designee (with a

copy to the UMB Conflict of Interest Officer and you) and include an implementation plan for any changes suggested by the Dean's designee.

- Service as an uncompensated member of the Scientific Advisory Board for Profectus is approved. In that role, you must recuse yourself from participating in decision-making involving UMB, including without limitation the consideration of issues involving University of Maryland technologies and research. Your Scientific Advisory Board activities for Profectus shall not involve the use of UMB funds or facilities, or personnel other than yourself.
- IHV members and members of their families together may not constitute, or have the authority to appoint, a majority of Profectus's Scientific Advisory Board or Board of Directors.
- Faculty, staff and trainees (graduate students and postdoctoral fellows) paid by or working in the IHV shall all receive notice annually from the Office of the Vice President for Academic Affairs that the Office is available for consultation regarding issues arising from the research and management of your financial interests affecting academic matters such as trainee mentorship and academic progress, intellectual property management, professional commitment, scientific publication, and promotion and tenure. Further, collaborators and prospective collaborators, including Members of the IHV and other persons, will be advised by the Office of the Vice President for Research and Development to discuss intellectual property terms with an individual from the Commercial Ventures and Intellectual Property division of the UMB Office of Research and Development before engaging in research with IHV Members or other persons working in or supported by the IHV.
- You and all of the research personnel and activities in your laboratory, and in the IHV, must be supported according to the level of effort and use, respectively, on various projects, subject to the standard Departmental and School review and approval of related documentation (such as UMB Grant Routing Forms and Time and Effort Reports).
- The total of all equity interests in Profectus held by Members of the IHV and their families must be diluted to less than 25% (the amount to be determined by agreement between Dr Gallo and your Dean) of the company's total equity within twenty-four (24) months of the date of this Exemption.

Stock in Profectus must be held by you until the earliest of the following trigger events:

- upon arms-length acquisition of all the stock or assets of Profectus or as part of a public offering of founders' shares; or
- upon approval by the President of UMB of a written request for permission to sell or transfer the stock, if the President determines there is

an acceptably low level of conflict of interest due to changed circumstances.

- You must file timely annual reports with the Conflict of Interest Officer, and respond promptly to any requests the Officer makes for revision of your disclosures.
- If you are, or become, an Investigator on NIH-sponsored research grants, UMB is required to disclose your financial interests and report that the resulting conflict of interest has been managed to the U.S. Public Health Service. The Conflict of Interest Officer will contact you regarding this requirement.

This Exemption is valid only with your agreement to the conditions upon which it is granted, as indicated by your signature below.

Note that this Exemption may be voided by me in the event of your failure to satisfy all of the foregoing conditions. Procedural questions regarding this Exemption should be directed to the UMB Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

I believe this Exemption permits your association with Profectus in a manner that comports with the requirements of the Maryland Public Ethics Law as well as University System of Maryland and UMB policy, provided that the conditions set out in the Exemption are observed. Any significant change in your planned relationship with Profectus, as disclosed in your exemption request, must be promptly disclosed to UMB (through your Dean), so that the effect of the change in circumstances may be determined. I recommend you disclose and discuss proposed changes prospectively to avoid potential withdrawal of this Exemption.

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Understood and Agreed To  
Anthony DeVico, Ph.D.

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Date

PC: Dr. F. Calia  
Mr. J. Giffels  
Dr. B. Jarrell  
Dr. M. Orlin  
Dr. E. A. Reece

EXEMPTION REQUEST FORM  
DISCLOSING CONFLICT OF INTEREST  
RELATED TO RESEARCH OR DEVELOPMENT

**PART TWO:**

**DISCLOSURE AND EXEMPTION REQUEST**

Please provide all information in boldface type.

**Section One.** Directory Information. Supply the requested information about yourself, as the employee requesting the exemption, and about the entity with which your relationship is proposed:

A. About You

Name: Anthony DeVico, PhD

University Title: **Professor of Medicine**

Division/Department or Administrative Unit: **IHV/SOM**

FTE: 1.0 Annual Salary: 139,639

University Business Address: **725 West Lombard Street, N660,  
Baltimore, MD 21201**

Phone Number: **410 706 4680**

Facsimile: **410 706 4694**

E-mail Address: devico@umbi.umd.edu

B. About Your Immediate Supervisor

Name: Robert C. Gallo, MD

University Title: **Professor and Director, IHV**

University Business Address: 725 West Lombard Street, S307,  
Baltimore, MD 21201

Phone Number: **410 706 8614**

Facsimile: **410 706 1952**

E-mail Address: gallo@umbi.umd.edu

C. About the Entity

Name: Profectus Biosciences, Inc.

Form of Organization: Corporation  
(e.g., LLC, corporation, partnership)

State in which it is organized: DE

General nature of its business activities: Research and Development

Any other names under which it does business, and the names of any wholly owned subsidiaries, or corporate parents (companies which own the entity) which conduct business similar to the entity's business, or which also have relationships with UM or you. n/a

**Profectus BioSciences, Inc. was originally named Maryland BioTherapeutics, Inc.**

A Contact Person: Give the name and title of an officer or other person at the entity or its parent who is informed about the proposed relationship:

**Mr. Joe Berardino, Chairman, CEO**

Give the person's business address: **techcenter@UMBC, 1450 South Rolling Road, Baltimore, MD 21227**

Telephone Number: **443 543 5010**

Facsimile Number: **443 543 5013**

E-Mail Address: **berardino@profectusbiosciences.com**

D. Additional Information

Is the entity an ongoing business concern?  yes  no

If the entity is to be established, (a) when do you think it will be created? \_\_\_\_\_ (give month and year)

(b) What state will it be organized in? \_\_\_\_\_

**Section Two. Your Conflict of Interest Concerns.** Supply information about the potential or actual conflict of interest and your proposal to mitigate it.

**A. Description of Conflict of Interest.** Describe in your own words the potential or actual conflict of interest which you or others have identified which led you to file this exemption request.

Use the space provided, or attach a statement. You may attach supporting documents as helpful.

I am a shareholder in ProfectusBiosciences and a member of their Scientific Advisory Board. I am also an inventor on technologies that have been licensed to Profectus by UMBI. I also participate in research collaborations with the company and we are co-investigators on SBIR, MIPS, and NIH R01/U01 grants and grant applications. As such, I will be presenting data in the form of grant applications, meeting presentations, and publications on technologies in which I have a financial interest.

My financial interest in Profectus and the technology may be perceived to affect or be affected by the research I am involved in.

B. Steps to Mitigate Conflict. Describe in your own words what steps you think UM could take to ensure that the integrity of your UM work is not compromised by your relationship with the entity. Be thorough. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

In my positions with IHV and Profectus, I will not be involved in the negotiations between UMB with Profectus to establish any terms of commercialization and I will excuse myself from any such discussions in any capacity. Additionally, I will neither advise nor participate in any decision-making in my capacity as an Profectus Scientific Advisory Board member that would affect UMB. I will disclose my interest in Profectus whenever I am presenting the results of my research.

Have you discussed these suggestions with the entity (y/n)? **yes**

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)? **n/a**\_\_\_\_\_

**Section Three.** Research and Development Activities. Explain how, in your view, the exemption will advance the research and development goals of the Public-Private Partnership Act. What are the research and development activities of the entity? In providing this information, remember that the UM Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development define "research" and "development" as basic or applied research or development, including (A) the development or marketing of university-owned technology or intellectual property; (B) the acquisition of services of an official or employee by an entity for research and development purposes; or (c) participation in State economic development programs. Research does not have to be sponsored research in order for relationships with entities to be eligible for Public-Private Partnership Act exemptions.

As per the Commercialization Agreement that created the IHV, Drs. Gallo, Blattner and Redfield were encouraged to establish one or more entities to commercialize products developed at the IHV. Profectus is developing a prophylactic vaccine and a therapeutic for HIV infection around technology developed at the IHV for which it has negotiated license agreements with UMBI and UMB.

Section Four. Details of Relationship. Provide information about the entity's relationship, present and/or proposed, with UM, and the entity's present or proposed interest in your work at UM.

As per the Commercialization Agreement Drs. Gallo, Blattner and Redfield have designated several technologies developed at the IHV to Profectus. UMB and UMBI have negotiated license agreements for these technologies with Profectus. UMBI and UMB have granted licenses to Profectus to make use and sell products developed under the terms of the licenses. I am an inventor on 2 technologies currently licensed to Profectus and I currently perform direct research utilizing these technologies.

A. Sponsored Research Agreements. Describe any present or proposed sponsored research agreements with the entity, as sponsor or as subcontractor to UM, involving you or your laboratory or academic group. Give the approximate budget, the Principal Investigator, the title of the project, and the name of the UM grants and contracts administrator most familiar with the project.

**1. Gates Foundation**

**Sterilizing Protection Elicited by an HIV-1 Vaccine**

**Robert Gallo**

**Pending**

**Request: \$15,000,000**

B. Options or License Agreements. Describe any present or proposed options or license agreements known to you between UM and the entity if such agreements relate to inventions or other intellectual property developed by you or in your laboratory or academic group, giving the title of the subject intellectual property.

**It is my understanding that Profectus has licensed the following technologies from UMBI or UMB:**

**Cell Cycle Agents:**

Parent PCT Application No:  
PCT/US03/28697  
  
(Redfield 00-015 PCT)  
  
COMPOSITIONS FOR INDUCING  
INCREASED LEVELS OF  $\beta$ -  
CHEMOKINES AND METHODS OF  
USE THEREFOR  
  
Entered National Phase on 3/13/2005

U.S. Patent Application No. 10/527,904  
  
COMPOSITIONS FOR INDUCING  
INCREASED LEVELS OF  $\beta$ -  
CHEMOKINES AND METHODS OF  
USE THEREFOR  
  
Still in prosecution stage

Redfield 00-015 Foreign Filing in  
Europe and Canada  
  
COMPOSITIONS FOR INDUCING  
INCREASED LEVELS OF  $\beta$ -  
CHEMOKINES AND METHODS OF  
USE THEREFOR  
  
Still in prosecution stage

Parent PCT Application No:  
PCT/US04/15681  
  
(Redfield 03-008 PCT).  
  
COMPOSITIONS FOR DOWN-  
REGULATION OF CCR5 EXPRESSION  
AND METHODS OF USE THEREFOR  
  
Entered into National Phase on 11/16/2005

U.S. Patent Application No. TBD  
Filed on 11/16/2005  
  
COMPOSITIONS FOR DOWN-  
REGULATION OF CCR5  
EXPRESSION AND METHODS OF  
USE THEREFOR  
  
Still in prosecution stage

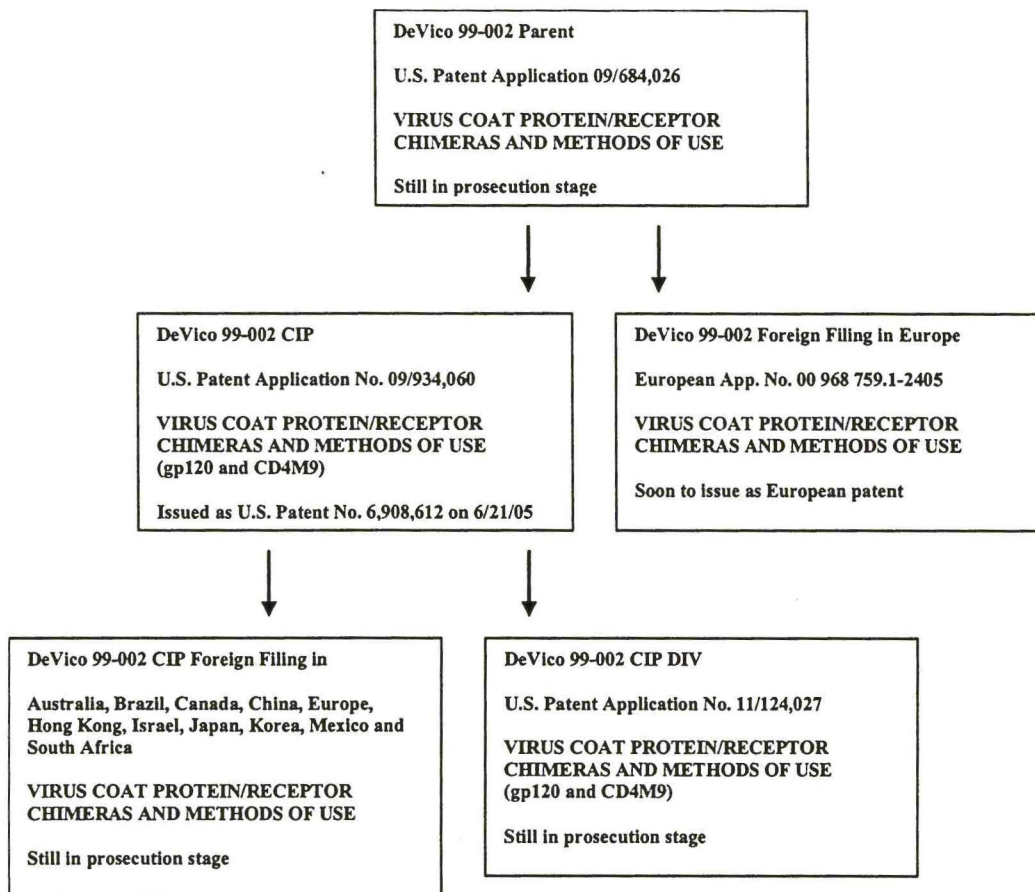
Redfield 03-00 Foreign Filing in  
Australia, Brazil, Canada, China,  
Europe, India, Mexico and Russia  
  
COMPOSITIONS FOR DOWN-  
REGULATION OF CCR5  
EXPRESSION AND METHODS  
OF USE THEREFOR  
  
Still in prosecution stage

Parent PCT Application No:  
PCT/US00/22170  
  
(Redfield 99-001 PCT)  
  
COMPOSITIONS FOR TREATING VIRAL  
INFECTIONS, AND METHODS THEREFOR

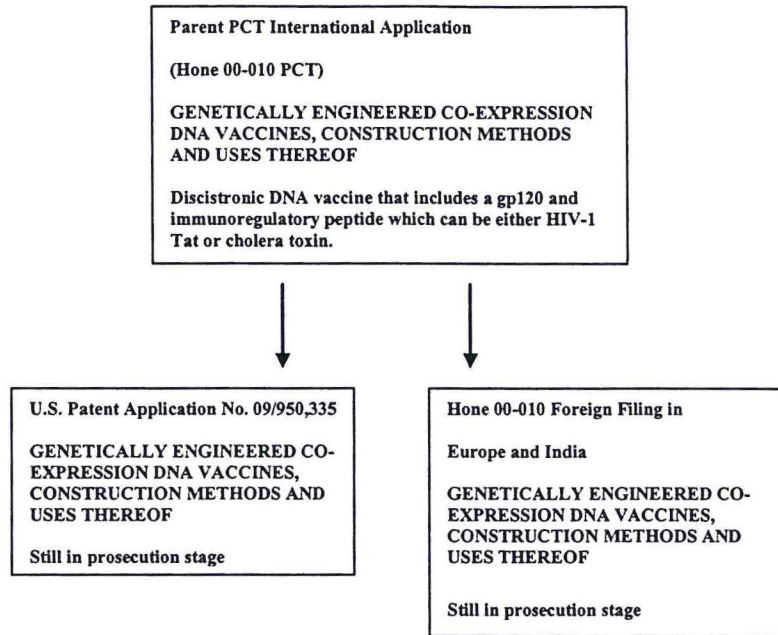
U.S. Patent Application No. 09/637,652  
  
COMPOSITIONS FOR TREATING VIRAL  
INFECTIONS, AND METHODS THEREFOR  
  
Issued as U.S. Patent No. 6,479,466 on 11/12/2002

Redfield 99-001 Foreign Filing in  
Europe, Canada and Australia  
  
COMPOSITIONS FOR TREATING VIRAL  
INFECTIONS, AND METHODS THEREFOR  
  
European patent was granted and validated in  
the United Kingdom only. Canada and  
Australia filings still in prosecution stage.

***HIV Vaccine/Viral Entry Inhibitors:***



*Vectored Vaccine Adjuvants:*



C. Entity Interest in Outcome. If, to your knowledge, the entity is interested in the outcome of your research or academic work, but is not a sponsor of your work, explain why the entity has such interest, in your opinion.

D. Gifts or Grants. If the entity has made gifts or grants to UM or the University of Maryland Foundation (UM Fund) in support of your work at UM, give information about the dates and amounts of the gifts or grants, including whether or not the funds were used for any purpose related to your proposed relationship with the entity.

**Section Five. Ownership Information**. If you are requesting an exemption permitting you to have an ownership interest in an entity, provide the requested information, and attach a copy of any written proposal or offer covering the ownership interest.

A. What "units" you will or may own. (E.g., stock, warrants, limited partnership interest, LLC interest.)

B. Ownership.

Individual   X   Joint       

If joint, name of co-owner: \_\_\_\_\_

C. Value of your Ownership Interest. Current estimated dollar value **\$500,000 not discounted for non-liquidity**. Percent of total ownership **2.4% on a fully diluted basis**.

**Common shares: 499,970**

D. Conditions of Ownership. Describe any conditions or encumbrances affecting your ownership interest. (E.g., will you be prohibited from exercising options or selling stock for a certain period of time, or until certain events occur?)

**Pursuant to a Shareholders Agreement I must first offer any stock I wish to sell to the other Profectus Shareholders. Additionally, the other Profectus Shareholders have a right on a prorated basis to participate in any sale of stock that I make to any other party.**

E. Will you purchase the ownership interest? (Y/N)        If so, what will you pay for it? \_\_\_\_\_ How does that price compare with the market value, if there is a market value?

In 2004 I purchased 499,970 shares of Profectus Common for \$.005 per share for a total of \$2498.50. This was the market value as determined by the board of directors of Profectus.

F. If you are not purchasing the ownership interest, what is the consideration for the ownership interest?

G. From what person or organization will you acquire your ownership interest?

**My common stock was acquired directly from the Company.**

**Section Six. Your Employment Relationship.** If you are requesting an exemption for an employment relationship (including both traditional compensated employment and other relationships e.g., consulting, office or executive responsibility in the entity's operations, board membership, royalties, etc.), attach a copy of any written proposal or offer covering the employment relationship and provide the requested information:

A. What position will you hold? What duties will you have on behalf of the entity? Be as specific as possible. In particular, if you will be conducting any research or scientific work for the entity, address what you will be doing, where you will do it, and the relationship, if any, to your work at UM.

Title: **Member of the Profectus Scientific Advisory Board**  
Responsibilities:

**The Scientific Advisory Board will be charged with advising the board of directors of the Company about setting the overall scientific mission and agenda of the Company and to review current and proposed program areas. My position is one of providing advice to the Company and not one of final decision or policy making for the Company. In my position as a member of the scientific advisory board I may be asked to review research grants submitted by the company including but no limited to grants intended to be submitted to the NIH but it is not intended that I will act as a principal investigator in any grants submitted by the Company at this time.**

**As described above I have received grant funds to perform research for and with Profectus. The research will be performed in my laboratory and all the costs associated with this research are recovered from the grant funds.**

B. How much time per biweekly period \_\_\_\_\_, month \_\_\_\_\_, year \_\_\_\_\_ will you be providing to the entity? \_\_\_\_\_

**I anticipate that I will provide services to MBTI one day per month.**

C. What compensation, if any, do you expect from the entity?

**None**

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) **Yes**\_\_\_\_\_ If no, please explain.

E. Are you requesting a leave of absence or change in level of FTE at UM in order to make your time available to the entity? (Y/N) **NO** If available, attach a copy of the request you have made and the approval.

F. If you are an externally funded investigator, what percentage of your FTE is budgeted to grants and contracts at this time?

**75%**

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**Section Seven.** Gifts. Describe any gifts for which you are requesting an exemption because of your relationship with the donating entity, or that entity's interest in your work.

If you are seeking permission to accept a gift or honorarium from an entity which has a relationship with you, or an interest in your work, provide the nature and value of the gift. You need to give this information whether you are considering a gift directly to you which you plan to retain, a gift you plan to give to another person or entity (e.g., assigning the gift to the UM Fund), or a gift arranged through you but directed to the UM Fund or other UM affiliates which can hold and administer funds for the benefit of your work.

Give the nature and value of the gift (cash, stock, etc.; market value or face value), and attach a copy of any written offer.

**Section Eight.**

A. Other Relationships with the Entity. Provide information about any other relationship with the entity which has not been discussed above, but which may require an exemption to be lawful. Include here matters such as employment of a spouse or dependent child by the entity, ownership of an interest in the entity by a spouse, dependent

child, or other dependent, or relationships between the entity and other organizations with which you or your spouse or dependent child have ownership or employment relationships. In describing ownership interests, give details, including percentage interest and value. In describing employment, give levels of effort and salary.

**None**

B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption request.

**None**

**Section Nine. Signature and Approvals.**

Before routing this form, execute it here. Please remind other reviewers to consider this form thoughtfully, complete their sections below, and execute the form if they are forwarding your request with a positive recommendation. Omit any steps of review which are not applicable to you. Be sure the last reviewer forwards the exemption request to the Conflict of Interest Officer.

A. I hereby make oath or affirm that the contents of this Exemption Request are true and correct to the best of my knowledge, information and belief.

  
\_\_\_\_\_  
Your Signature

6/29/07  
\_\_\_\_\_  
Date





**UNIVERSITY OF MARYLAND**


Office of the President

DAVID J. RAMSAY, DM, DPhil  
President

520 West Lombard Street  
Baltimore, Maryland 21201-1627  
410 706 7002 | 410 706 0500 FAX

**MEMORANDUM**

TO: Robert C. Gallo, MD  
Director  
Institute of Human Virology  
School of Medicine

FROM: David J. Ramsay, D.M., D.Phil.  
President 

RE: Conflict of Interest Disclosure #01-08-001

DATE: January 22, 2008

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated July 31, 2007. Your request involves proposed relationships between you and Profectus Biosciences, Inc. (Profectus). You propose compensated service on Profectus’s Scientific Advisory Board and ownership of equity in Profectus. In addition, Profectus is anticipated to license technologies invented by you and by personnel affiliated with the Institute of Human Virology (IHV) and which are owned by the University of Maryland Baltimore (UMB). As an inventor you stand to receive a share of institutional royalties as a result of the licenses of your inventions. As a shareholder of Profectus, you stand to benefit from the license of the inventions of your colleagues.

These proposed relationships present a conflict of interest because you plan to participate as a UMB investigator on research of interest to, and possibly supported by Profectus, and because other personnel of the IHV may participate in such research.

As Director of the IHV, it is important that your role on behalf of the IHV be your primary professional obligation, and that your associations with Profectus not appear to impair, or actually impair, your activities on behalf of the IHV and your academic freedom and objectivity as a member of the School of Medicine faculty.

I find that your association with Profectus will facilitate research and development. I have determined that your relationship with Profectus would not be a harmful interest, as described in the USM Board of Regents’ Policy on Conflicts of Interest in Research and Development, provided you comply with the conditions set out in this Exemption. This Exemption permits your association with Profectus as described in your exemption request, with the exceptions listed below. This Exemption is valid from the date of this memorandum through January 7, 2009. Further extension of this Exemption, with or without revision, will be considered, but not guaranteed, for the period beginning January 8, 2009.

In the absence of this Exemption, or in the event you do not comply with the conditions set out in this Exemption, your association with Profectus will conflict with the Maryland Public Ethics Law, as well as University System of Maryland and UMB policy, rendering you subject to disciplinary action and other penalties allowed by State law and UMB and USM policy.

The conditions of this Exemption follow:

- All of your business and financial relationships with Profectus must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and research subjects) participating in your research, and to sponsors of your research. The requirement will apply whether or not Profectus is a research sponsor, and whether or not it is directly involved in the research. Your relationships with Profectus must also be disclosed whenever you publish or speak about the research, including during informal presentations made on or off campus, such as departmental seminars. Disclosure shall include enough detail of the business aspects of your Profectus relationships to enable an understanding of the significance of the relevant financial relationships. The statement of disclosure must be approved by the campus conflict of interest officer. UMB will review the disclosure annually and you will modify it as required given any changes in your relationships to Profectus. This Exemption shall be posted to UMB's public web site, shall be placed on file in the Health Sciences and Human Services Library, and will be in the public records of the State Ethics Commission.
- It is my understanding that you are not currently involved as an investigator in research involving human subjects. In the event that you do become involved in the future, you may not serve as the principal investigator for research involving human subjects where that research is of interest to Profectus. A principal investigator, a qualified scientist, must be identified who is not in the IHV and who does not have a similar financial interest related to the research. Your agreement to adhere to this plan must be clearly documented prior to the initiation of the study and must be part of the IRB proposal.
- For all research in which you are involved, all research records (including notebooks, computers, data, etc) must be available for inspection by the Dean's designee and UMB officials and research lab meetings shall be open to these same individuals. In addition, all research must be conducted according to Good Laboratory Practices.
- At least annually, the Dean's designee will schedule a meeting with you to discuss the research and conflict of interest issues to ensure the integrity of the research. The Dean's designee may enlist the expertise of other UMB scientists, or consultants to UMB, as necessary to evaluate the research and financial interests. These discussions will be documented in writing by the Dean's designee (with a

copy to the UMB Conflict of Interest Officer and you) and include an implementation plan for any changes suggested by the Dean's designee.

- You may not serve as the Chair of Profectus's Scientific Advisory Board. The Chair must be someone who is independent of your UMB position and activities. Service as a member (but not the Chair) of the Scientific Advisory Board for Profectus is approved, however. In that role, you must recuse yourself from participating in decision-making involving UMB, including without limitation the consideration of issues involving University of Maryland technologies and research. Your Scientific Advisory Board activities for Profectus shall not involve the use of UMB funds or facilities, or personnel other than yourself.
- IHV members and members of their families together may not constitute, or have the authority to appoint, a majority of Profectus's Scientific Advisory Board or Board of Directors.
- Faculty, staff and trainees (graduate students and postdoctoral fellows) paid by or working in the IHV shall be notified annually by the Conflict of Interest Officer that he is available for consultation regarding issues arising from the research and management of your financial interests affecting academic matters such as trainee mentorship and academic progress, intellectual property management, professional commitment, scientific publication, and promotion and tenure. Further, you must refer all collaborators and prospective collaborators, including Members of the IHV and other persons, to Michael Rollor in the Commercial Ventures and Intellectual Property division of the UMB Office of Research and Development to discuss intellectual property terms before engaging in research with IHV Members or other persons working in or supported by the IHV.
- You and all of the research personnel and activities in your laboratory, and in the IHV, must be supported according to the level of effort and use, respectively, on various projects, subject to the standard Departmental and School review and approval of related documentation (such as UMB Grant Routing Forms and Time and Effort Reports). You may not approve contribution of time and effort, or discount of direct or indirect costs, in agreement with Profectus or its sublicensees.
- The total of all equity interests in Profectus held by Members of the IHV and their families must be diluted to less than 25% (the amount to be determined by agreement between you and your Dean) of the company's total equity within twenty-four (24) months of the date of this Exemption.

Stock in Profectus must be held by you until the earliest of the following trigger events:

- upon arms-length acquisition of all the stock or assets of Profectus or as part of a public offering of founders' shares; or

- upon approval by the President of UMB of a written request for permission to sell or transfer the stock, if the President determines there is an acceptably low level of conflict of interest due to changed circumstances.
- You must file timely annual reports with the Conflict of Interest Officer, and respond promptly to any requests the Officer makes for revision of your disclosures.
- As you are an Investigator on NIH-sponsored research grants, UMB is required to disclose your financial interests and report that the resulting conflict of interest has been managed to the U.S. Public Health Service. The Conflict of Interest Officer will contact you regarding this requirement.

This Exemption is valid only with your agreement to the conditions upon which it is granted, as indicated by your signature below.

Note that this Exemption may be voided by me in the event of your failure to satisfy all of the foregoing conditions. Procedural questions regarding this Exemption should be directed to the UMB Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

I believe this Exemption permits your association with Profectus in a manner that comports with the requirements of the Maryland Public Ethics Law as well as University System of Maryland and UMB policy, provided that the conditions set out in the Exemption are observed. Any significant change in your planned relationship with Profectus, as disclosed in your exemption request, must be promptly disclosed to UMB (through your Dean), so that the effect of the change in circumstances may be determined. I recommend you disclose and discuss proposed changes prospectively to avoid potential withdrawal of this Exemption.

---

Understood and Agreed To  
Robert C. Gallo, M.D.

---

Date

PC: Mr. J. Giffels  
Dr. B. Jarrell  
Dr. M. Orlin  
Dr. E. A. Reece

EXEMPTION REQUEST FORM  
DISCLOSING CONFLICT OF INTEREST  
RELATED TO RESEARCH OR DEVELOPMENT

**PART TWO:**

**DISCLOSURE AND EXEMPTION REQUEST**

Please provide all information in boldface type.

**Section One.** Directory Information. Supply the requested information about yourself, as the employee requesting the exemption, and about the entity with which your relationship is proposed:

A. About You

Name: **Robert C. Gallo, M.D.**

University Title: **Professor, Director IHV**

Division/Department or Administrative Unit: **IHV/SOM** \_\_\_\_\_

FTE: \_\_\_\_\_ Annual Salary: \_\_\_\_\_

University Business Address: **725 West Lombard Street**

**Baltimore, MD 21201**

Phone Number: **410 706 8614**

Facsimile: **410 706 1983**

E-mail Address: **gallo@umbi.umd.edu** \_\_\_\_\_

B. About Your Immediate Supervisor

Name: \_\_\_\_\_

University Title: \_\_\_\_\_

University Business Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Facsimile: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

C. About the Entity

Name: ProfectusBiosciences, Inc.

Form of Organization: Corporation  
(e.g., LLC, corporation, partnership)

State in which it is organized: DE

General nature of its business activities: **Research and Development: Profectus is developing therapeutics and vaccines to reduce the morbidity and mortality caused by human viral diseases and, in particular, by the human immunodeficiency virus, the causative agent of the acquired immunodeficiency syndrome. Initially the Company will focus on the further development and commercialization of certain prophylactic and therapeutic vaccines and therapeutics that were originally developed by scientists at the Institute of Human Virology (the "IHV"). As the Company matures, it intends to partner or establish co-development and marketing arrangements with other companies to develop technologies with commercial application to viral diseases, including HIV.**

Any other names under which it does business, and the names of any wholly owned subsidiaries, or corporate parents (companies which own the entity) which conduct business similar to the entity's business, or which also have relationships with UM or you. n/a

**ProfectusBioSciences, Inc. was originally named Maryland BioTherapeutics, Inc.**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

A Contact Person: Give the name and title of an officer or other person at the entity or its parent who is informed about the proposed relationship:

**Mr. Joe Berardino, Chairman, CEO**

Give the person's business address: **techcenter@UMBC, 1450 South Rolling Road, Baltimore, MD 21227**

Telephone Number: **443 543 5010**

Facsimile Number: **443 543 5013**

E-Mail Address: **berardino@profectusbiosciences.com**

**Section Two. Your Conflict of Interest Concerns.** Supply information about the potential or actual conflict of interest and your proposal to mitigate it.

**A. Description of Conflict of Interest.** Describe in your own words the potential or actual conflict of interest which you or others have identified which led you to file this exemption request. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

**I am a co-founder of Profectus BioSciences, Inc. Profectus was set up with the intention of being one of the companies to be "Designated" (as that term is defined in the Commercialization Agreement as executed by UMB, UMBI and Drs. Blattner, Redfield, myself and others) for select technologies developed at the IHV. Once Profectus is Designated for a particular technology the University and Profectus will enter into a predefined negotiation process with the anticipated outcome of a commercial license being granted to Profectus. With that anticipated outcome Profectus will be charged with commercially developing the technology. In this situation Profectus will likely want to develop a sponsored research agreement with the IHV to continue work on any technology it may license from UMB.**

**Either through the direct licensing of technology to Profectus from UMB or by virtue of a sponsored research agreement between both parties, Profectus will have a direct interest in research being performed within the IHV. It is also anticipated that Profectus will file for federally funded grants including but not limited to SBIR and STTR grants intended to benefit small commercial entities and that in many cases IHV/UMB will be a subcontractor to the Company. It is also possible that Drs. Blattner, Redfield and I may Designate additional technologies to Profectus in the future, however, this is not guaranteed and will be decided by us on a technology by technology basis.**

**In my current position as Director of the IHV, I am responsible for setting the programmatic and/or scientific areas of research within the IHV. In my positions with IHV and Profectus, I will not be involved in the negotiations between UMB and Profectus to establish any terms of commercialization and I will excuse myself from any such discussions in any capacity.**

**The IHV maintains an independent scientific advisory board which meets at least once yearly. This scientific advisory board of the IHV will be used to manage my conflicts with Profectus. This board reviews the scientific programs and directions of the IHV at its meetings. It is also responsible to review and comment on changes in faculty status. The board also reviews the budget and the budget allocations of each of the project areas and makes recommendations on any suggested changes. The Dean of the School of Medicine will receive a copy of the report prepared by the board after its review. The reports will disclose the relationship I have with Profectus and any suggestions to manage this conflict.**

With respect to any clinical trials performed by the IHV on behalf of Profectus or on any products that Profectus has an interest in, the following will also be adhered to:

1. An independent safety analysis will be done by an independent medical monitor, safety committee or DSMB as appropriate for the level of the trial being conducted.
2. All data from the trial will be analyzed by an independent statistician.
3. All post trial dissemination of data will be reviewed and approved by an independent statistician or committee.

Profectus currently has a Board of Directors containing 9 members. Pursuant to a Profectus Shareholders Agreement I am permitted to appoint 3 of the 9 members.

B. Steps to Mitigate Conflict. Describe in your own words what steps you think UM could take to ensure that the integrity of your UM work is not compromised by your relationship with the entity. Be thorough. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

**In my positions with IHV and Profectus, I will not be involved in the negotiations between UMB with Profectus to establish any terms of commercialization and I will excuse myself from any such discussions in any capacity. Additionally, I will neither advise nor participate in any decision-making in my capacity as a Profectus Scientific Advisory Board member that would affect UMB. I will disclose my interest in Profectus whenever I am presenting the results of my research.**

Have you discussed these suggestions with the entity (y/n)? yes

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)? n/a\_\_\_\_\_

**Section Three.** Research and Development Activities. Explain how, in your view, the exemption will advance the research and development goals of the Public-Private Partnership Act. What are the research and development activities of the entity? In providing this information, remember that the UM Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development define "research" and "development" as basic or applied research or development, including (A) the development or marketing of university-owned technology or intellectual property; (B) the acquisition of services of an official or employee by an entity for research and development purposes; or (c) participation in State economic development programs. Research does not have to be sponsored research in order for relationships with entities to be eligible for Public-Private Partnership Act exemptions.

**As per the Commercialization Agreement that created the IHV, Drs. Blattner, Redfield and I were encouraged to establish one or more entities to commercialize products developed at the IHV. Profectus is developing a prophylactic vaccine and a therapeutic for HIV infection around technology developed at the IHV for which it has negotiated license agreements with UMBI and UMB.**

**Section Four.** Details of Relationship. Provide information about the entity's relationship, present and/or proposed, with UM, and the entity's present or proposed interest in your work at UM.

**As per the Commercialization Agreement Drs. Blattner, Redfield and I have Designated several technologies developed at the IHV to Profectus. UMB and UMBI have negotiated license agreements for these technologies with Profectus. UMBI and UMB have granted licenses to Profectus to make use and sell products developed under the terms of the licenses. The IHV currently performs direct research utilizing these technologies.**

A. Sponsored Research Agreements. Describe any present or proposed sponsored research agreements with the entity, as sponsor or as subcontractor to UM, involving you or your laboratory or academic group. Give the approximate budget, the Principal Investigator, the title of the project, and the name of the UM grants and contracts administrator most familiar with the project.

1. **Maryland Industrial Partnership**

Granted: Feb 1, 2007 for 1 year

Cholera A1 Subunit as an HIV DNA Vaccine Adjuvant

Ken Bagley, Profectus/ George Lewis, UMB

Budget: \$225,622

2. **Maryland Industrial Partnership**

Granted: August 1, 2006 for 1 year

Developing Rapamycin to Treat HIV Infection

Tim Fouts, Profectus/ George Lewis, UMB

Budget: \$200,000

3. **National Institutes of Health**

NIAID

Enhancing DNA Vaccines Using Modified Cholera Like Toxin A1 Subunits and adjuvants

Tim Fouts, Profectus PI

Granted: June 1, 2007 for 1 year

Budget: \$294,643

4. **Gates Foundation**

Sterilizing Protection Elicited by an HIV-1 Vaccine

Robert Gallo

Pending

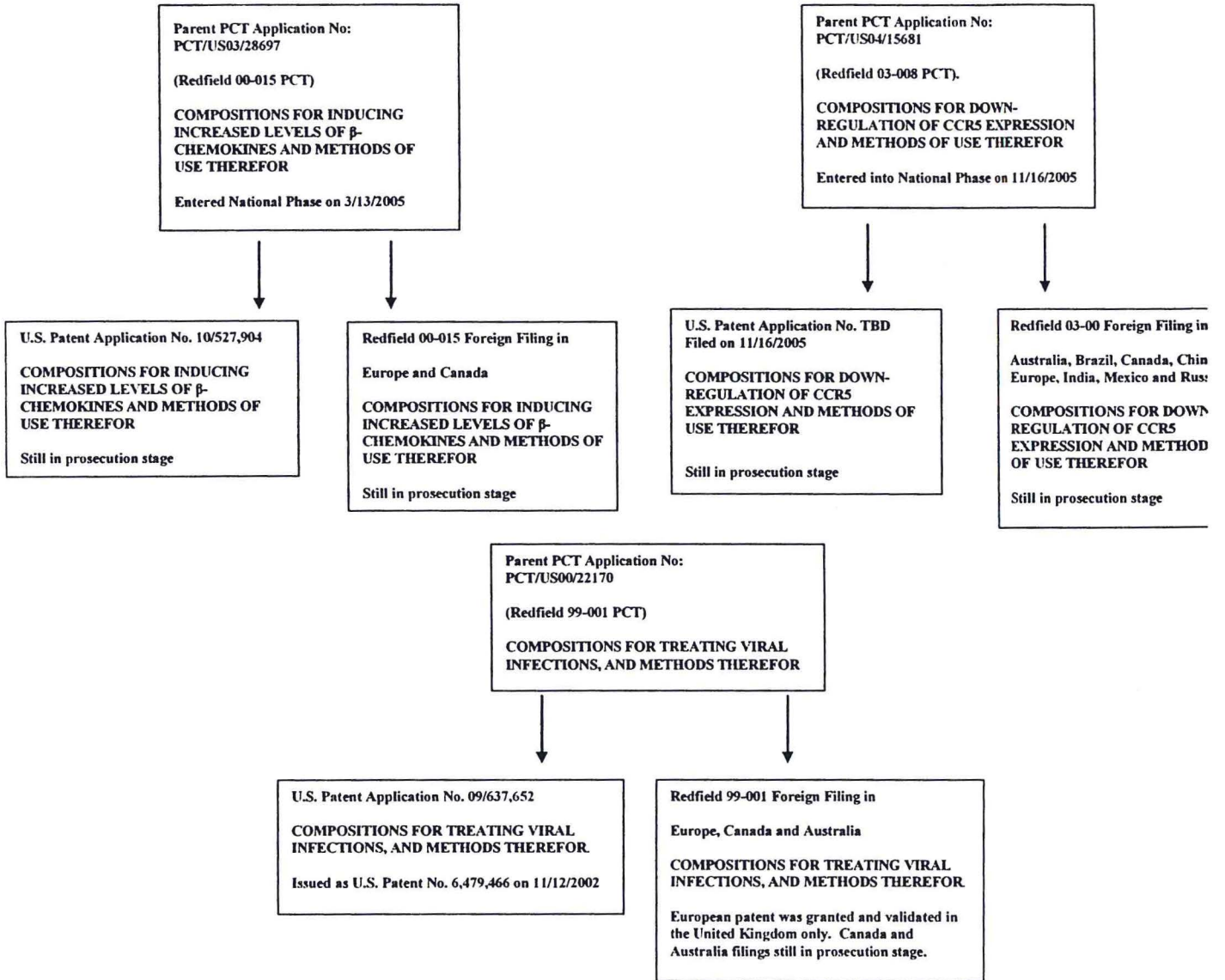
Request: \$15,000,000

B. Options or License Agreements. Describe any present or proposed options or license agreements known to you between UM and the entity if such agreements relate to inventions or other intellectual property developed by you or in your laboratory or academic group, giving the title of the subject intellectual property.

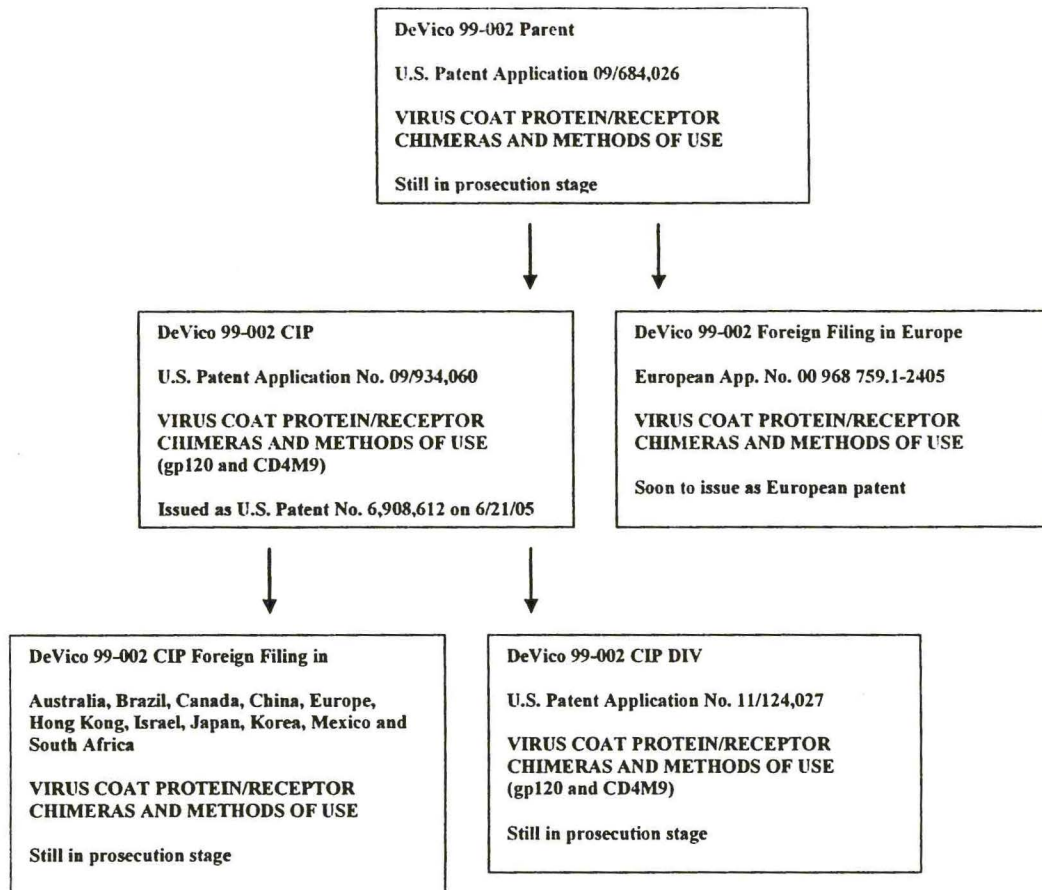
C.

It is my understanding that Profectus has licensed the following technologies from UMBI or UMB:

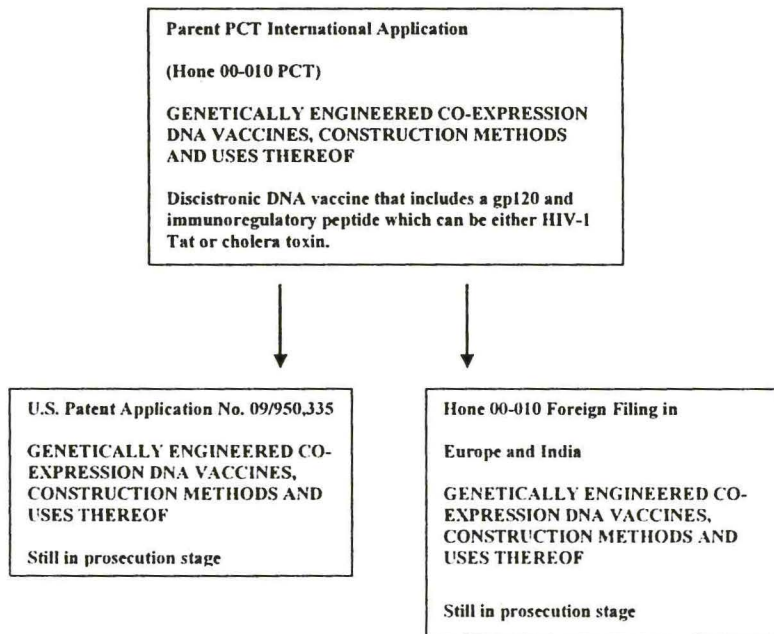
*Cell Cycle Agents:*



## *HIV Vaccine/Viral Entry Inhibitors:*



## *Vectored Vaccine Adjuvants:*



C. Entity Interest in Outcome. If, to your knowledge, the entity is interested in the outcome of your research or academic work, but is not a sponsor of your work, explain why the entity has such interest, in your opinion.

D. Gifts or Grants. If the entity has made gifts or grants to UM or the University of Maryland Foundation (UM Fund) in support of your work at UM, give information about the dates and amounts of the gifts or grants, including whether or not the funds were used for any purpose related to your proposed relationship with the entity.

**Section Five. Ownership Information.** If you are requesting an exemption permitting you to have an ownership interest in an entity, provide the requested information, and attach a copy of any written proposal or offer covering the ownership interest.

A. What "units" you will or may own. (E.g., stock, warrants, limited partnership interest, LLC interest.)

B. Ownership.

Individual   X   Joint \_\_\_\_\_

If joint, name of co-owner: \_\_\_\_\_

C. Value of your Ownership Interest. Current estimated dollar value **\$2.8 million, not discounted for non-liquidity**. Percent of total ownership **13.3% on a fully diluted basis**.

**Common shares: 2,800,040**

D. Conditions of Ownership. Describe any conditions or encumbrances affecting your ownership interest. (E.g., will you be prohibited from exercising options or selling stock for a certain period of time, or until certain events occur?)

**Pursuant to a Shareholders Agreement I must first offer any stock I wish to sell to the other Profectus Shareholders. Additionally, the other Profectus Shareholders have a right on a prorated basis to participate in any sale of stock that I make to any other party.**

E. Will you purchase the ownership interest? (Y/N) \_\_\_\_\_ If so, what will you pay for it? \_\_\_\_\_ How does that price compare with the market value, if there is a market value?

**In 2004 I purchased 2,800,040 shares of Profectus Common for \$.005 per share for a total of \$14,200.20. This was the market value as determined by the board of directors of Profectus.**

F. If you are not purchasing the ownership interest, what is the consideration for the ownership interest?

G. From what person or organization will you acquire your ownership interest?

**My common stock was acquired directly from the Company.**

**Section Six. Your Employment Relationship.** If you are requesting an exemption for an employment relationship (including both traditional compensated employment and other relationships e.g., consulting, office or executive responsibility in the entity's operations, board membership, royalties, etc.), attach a copy of any written proposal or offer covering the employment relationship and provide the requested information:

A. What position will you hold? What duties will you have on behalf of the entity? Be as specific as possible. In particular, if you will be conducting any research or scientific work for the entity, address what you will be doing, where you will do it, and the relationship, if any, to your work at UM.

Title: **Chair of the Profectus Scientific Advisory Board**  
Responsibilities:

The Scientific Advisory Board is charged with advising the Board of Directors of the Company about setting the overall scientific mission and agenda of the Company and to review current and proposed program areas. My position is one of providing advice to the Company and not one of final decision or policy making for the Company. In my position as Chair of the Scientific Advisory Board I may be asked to review research grants submitted by the company including but no limited to grants intended to be submitted to the NIH but it is not intended that I will act as a principal investigator in any grants submitted by the Company at this time.

As described above IHV has received grant funds to perform research for and with Profectus. The research will be performed in our laboratories and all the costs associated with this research are recovered from the grant funds.

B. How much time per biweekly period \_\_\_\_\_, month \_\_\_\_\_, year \_\_\_\_\_ will you be providing to the entity? \_\_\_\_\_

I anticipate that I will provide services to Profectus one day per month.

C. What compensation, if any, do you expect from the entity?

\$50,000 per year paid quarterly beginning April 1, 2006. I will also be reimbursed for any out-of-pocket expenses.

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) **Yes**\_\_\_\_\_ If no, please explain.

E. Are you requesting a leave of absence or change in level of FTE at UM in order to make your time available to the entity? (Y/N) **NO** If available, attach a copy of the request you have made and the approval.

F. If you are an externally funded investigator, what percentage of your FTE is budgeted to grants and contracts at this time?

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**Section Seven.** Gifts. Describe any gifts for which you are requesting an exemption because of your relationship with the donating entity, or that entity's interest in your work.

If you are seeking permission to accept a gift or honorarium from an entity which has a relationship with you, or an interest in your work, provide the nature and value of the gift. You need to give this information whether you are considering a gift directly to you which you plan to retain, a gift you plan to give to another person or entity (e.g., assigning the gift to the UM Fund), or a gift arranged through you but directed to the UM Fund or other UM affiliates which can hold and administer funds for the benefit of your work.

Give the nature and value of the gift (cash, stock, etc.; market value or face value), and attach a copy of any written offer.

**Section Eight.**

A. Other Relationships with the Entity. Provide information about any other relationship with the entity which has not been discussed above, but which may require an exemption to be lawful. Include her matters such as employment of a spouse or dependent child by the entity, ownership of an interest in the entity by a spouse, dependent child, or other dependent, or relationships between the entity and other organizations with which you or your spouse or dependent child have ownership or employment relationships. In describing ownership interests, give details, including percentage interest and value. In describing employment, give levels of effort and salary.

B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption request.

**Section Nine.** Signature and Approvals.

Before routing this form, execute it here. Please remind other reviewers to consider this form thoughtfully, complete their sections below, and execute the form if they are forwarding your request with a positive recommendation. Omit any steps of review which are not applicable to you. Be sure the last reviewer forwards the exemption request to the Conflict of Interest Officer.

A. I hereby make oath or affirm that the contents of this Exemption Request are true and correct to the best of my knowledge, information and belief.

*R Gallo*

\_\_\_\_\_  
Your Signature

4-31-07

Date





# UNIVERSITY OF MARYLAND


Office of the President

DAVID J. RAMSAY, DM, DPhil  
President

520 West Lombard Street  
Baltimore, Maryland 21201-1627  
410 706 7002 | 410 706 0500 FAX

## MEMORANDUM

**TO:** George Lewis, Ph.D.  
Professor of Microbiology and Immunology  
School of Medicine

**FROM:** David J. Ramsay, D.M., D.Phil.  
President 

**DATE:** January 22, 2008

**SUBJECT:** Conflict of Interest Disclosure #01-08-003

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated June 29, 2007. Your request involves proposed relationships between you and Profectus Biosciences, Inc. (Profectus). You propose uncompensated service on Profectus's Scientific Advisory Board and ownership of equity in Profectus. In addition, Profectus is anticipated to license technologies invented by you and which are owned by the University of Maryland Baltimore (UMB). As an inventor you stand to receive a share of institutional royalties as a result of the licenses of your inventions. As a shareholder of Profectus, you stand to benefit from the license of the inventions of your colleagues.

These proposed relationships present a conflict of interest because you plan to participate as a UMB investigator on research of interest to, and possibly supported by, Profectus.

I find that your association with Profectus will facilitate research and development. I have determined that your relationship with Profectus would not be a harmful interest, as described in the USM Board of Regents' Policy on Conflicts of Interest in Research and Development, provided you comply with the conditions set out in this Exemption. This Exemption permits your association with Profectus as described in your exemption request, with the exceptions listed below. This Exemption is valid from the date of this memorandum through January 22, 2009. Further extension of this Exemption, with or without revision, will be considered, but not guaranteed, for the period beginning January 23, 2009.

In the absence of this Exemption, or in the event you do not comply with the conditions set out in this Exemption, your association with Profectus will conflict with the Maryland Public Ethics Law, as well as University System of Maryland and UMB policy, rendering



you subject to disciplinary action and other penalties allowed by State law and UMB and USM policy.

The conditions of this Exemption follow:

- All of your business and financial relationships with Profectus must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and research subjects) participating in your research, and to sponsors of your research. The requirement will apply whether or not Profectus is a research sponsor, and whether or not it is directly involved in the research. Your relationships with Profectus must also be disclosed whenever you publish or speak about the research, including during informal presentations made on or off campus, such as departmental seminars. Disclosure shall include enough detail of the business aspects of your Profectus relationships to enable an understanding of the significance of the relevant financial relationships. The statement of disclosure must be approved by the campus conflict of interest officer. UMB will review the disclosure annually and you will modify it as required given any changes in your relationships to Profectus. This Exemption shall be posted to UMB's public web site, shall be placed on file in the Health Sciences and Human Services Library, and will be in the public records of the State Ethics Commission.
- You cannot be the principal investigator for research involving human subjects where that research is of interest to Profectus. A principal investigator, a qualified scientist, must be identified who is not in the IHV and who does not have a similar financial interest related to the research. Your agreement to adhere to this plan must be clearly documented prior to the initiation of the study and must be part of the IRB proposal.
- On a quarterly basis, you must submit detailed reports on research plans, progress and publications. The reports must include all research in which you are involved and must be submitted to the Dean or his designee for evaluation, with a copy to the UMB Conflict of Interest Officer. Research notebooks must be maintained according to Good Laboratory Practices, including the requirement that all pages of notebooks be signed by the person conducting the experiment and a witness or reviewer who can objectively review the information, but who is not integrally involved in the collection of the data. At all times, all research records (including notebooks, computers, data, etc) must be available for inspection by the Dean's designee and UMB officials and research lab meetings shall be open to these same individuals.
- At least annually, the Dean's designee will schedule a meeting with you to discuss the research and conflict of interest issues to ensure the integrity of the research. The Dean's designee may enlist the expertise of other UMB scientists, or consultants to UMB, as necessary to evaluate the research and financial interests. These discussions will be documented in writing by the Dean's designee (with a



copy to the UMB Conflict of Interest Officer and you) and include an implementation plan for any changes suggested by the Dean's designee.

- Service as an uncompensated member of the Scientific Advisory Board for Profectus is approved. In that role, you must recuse yourself from participating in decision-making involving UMB, including without limitation the consideration of issues involving University of Maryland technologies and research. Your Scientific Advisory Board activities for Profectus shall not involve the use of UMB funds or facilities, or personnel other than yourself.
- IHV members and members of their families together may not constitute, or have the authority to appoint, a majority of Profectus's Scientific Advisory Board or Board of Directors.
- Faculty, staff and trainees (graduate students and postdoctoral fellows) paid by or working in the IHV shall all receive notice annually from the Office of the Vice President for Academic Affairs that the Office is available for consultation regarding issues arising from the research and management of your financial interests affecting academic matters such as trainee mentorship and academic progress, intellectual property management, professional commitment, scientific publication, and promotion and tenure. Further, collaborators and prospective collaborators, including Members of the IHV and other persons, will be advised by the Office of the Vice President for Research and Development to discuss intellectual property terms with an individual from the Commercial Ventures and Intellectual Property division of the UMB Office of Research and Development before engaging in research with IHV Members or other persons working in or supported by the IHV.
- You and all of the research personnel and activities in your laboratory, and in the IHV, must be supported according to the level of effort and use, respectively, on various projects, subject to the standard Departmental and School review and approval of related documentation (such as UMB Grant Routing Forms and Time and Effort Reports).
- The total of all equity interests in Profectus held by Members of the IHV and their families must be diluted to less than 25% (the amount to be determined by agreement between Dr Gallo and your Dean) of the company's total equity within twenty-four (24) months of the date of this Exemption.

Stock in Profectus must be held by you until the earliest of the following trigger events:

- upon arms-length acquisition of all the stock or assets of Profectus or as part of a public offering of founders' shares; or
- upon approval by the President of UMB of a written request for permission to sell or transfer the stock, if the President determines there is



an acceptably low level of conflict of interest due to changed circumstances.

- You must file timely annual reports with the Conflict of Interest Officer, and respond promptly to any requests the Officer makes for revision of your disclosures.
- If you are, or become, an Investigator on NIH-sponsored research grants, UMB is required to disclose your financial interests and report that the resulting conflict of interest has been managed to the U.S. Public Health Service. The Conflict of Interest Officer will contact you regarding this requirement.

This Exemption is valid only with your agreement to the conditions upon which it is granted, as indicated by your signature below.

Note that this Exemption may be voided by me in the event of your failure to satisfy all of the foregoing conditions. Procedural questions regarding this Exemption should be directed to the UMB Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

I believe this Exemption permits your association with Profectus in a manner that comports with the requirements of the Maryland Public Ethics Law as well as University System of Maryland and UMB policy, provided that the conditions set out in the Exemption are observed. Any significant change in your planned relationship with Profectus, as disclosed in your exemption request, must be promptly disclosed to UMB (through your Dean), so that the effect of the change in circumstances may be determined. I recommend you disclose and discuss proposed changes prospectively to avoid potential withdrawal of this Exemption.

---

Understood and Agreed To  
George Lewis, Ph.D.

---

Date

PC: Mr. J. Giffels  
Dr. B. Jarrell  
Dr. J. Kaper  
Dr. M. Orlin  
Dr. E. A. Reece



EXEMPTION REQUEST FORM  
DISCLOSING CONFLICT OF INTEREST  
RELATED TO RESEARCH OR DEVELOPMENT

**PART TWO:**

**DISCLOSURE AND EXEMPTION REQUEST**

Please provide all information in boldface type.

**Section One.** Directory Information. Supply the requested information about yourself, as the employee requesting the exemption, and about the entity with which your relationship is proposed:

A. About You

Name: George Lewis, PhD

University Title: **Professor of Microbiology and Immunology**

Division/Department or Administrative Unit: **IHV/SOM**

FTE: 1.0 Annual Salary: 178,000

University Business Address: **725 West Lombard Street, N660,  
Baltimore, MD 21201**

Phone Number: **410 706 4688**

Facsimile: **410 706 4695**

E-mail Address: **lewisg@umbi.umd.edu**

B. About Your Immediate Supervisor

Name: Robert C. Gallo, MD

University Title: **Professor and Director, IHV**

University Business Address: **725 West Lombard Street, S307,  
Baltimore, MD 21201**

Phone Number: 410 706 8614

Facsimile: 410 706 1952

E-mail Address: gallo@umbi.umd.edu

C. About the Entity

Name: Profectus Biosciences, Inc.

Form of Organization: Corporation  
(e.g., LLC, corporation, partnership)

State in which it is organized: DE

General nature of its business activities: Research and Development

Any other names under which it does business, and the names of any wholly owned subsidiaries, or corporate parents (companies which own the entity) which conduct business similar to the entity's business, or which also have relationships with UM or you. n/a

**Profectus BioSciences, Inc. was originally named Maryland BioTherapeutics, Inc.**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

A Contact Person: Give the name and title of an officer or other person at the entity or its parent who is informed about the proposed relationship:

**Mr. Joe Berardino, Chairman, CEO**

Give the person's business address: **techcenter@UMBC, 1450 South Rolling Road, Baltimore, MD 21227**

Telephone Number: 443 543 5010

Facsimile Number: 443 543 5013

E-Mail Address: **berardino@profectusbiosciences.com**

D. Additional Information

Is the entity an ongoing business concern?  X yes  no

If the entity is to be established, (a) when do you think it will be created? \_\_\_\_\_ (give month and year)

(b) What state will it be organized in? \_\_\_\_\_

**Section Two. Your Conflict of Interest Concerns.** Supply information about the potential or actual conflict of interest and your proposal to mitigate it.

**A. Description of Conflict of Interest.** Describe in your own words the potential or actual conflict of interest which you or others have identified which led you to file this exemption request. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

I am a shareholder in ProfectusBiosciences and a member of their Scientific Advisory Board. I am also an inventor on technologies that have been licensed to Profectus by UMBI. I also participate in research collaborations with the company and we are co-investigators on SBIR, MIPS, and NIH R01/U01 grants and grant applications. As such, I will be presenting data in the form of grant applications, meeting presentations, and publications on technologies in which I have a financial interest.

My financial interest in Profectus and the technology may be perceived to affect or be affected by the research I am involved in.

**B. Steps to Mitigate Conflict.** Describe in your own words what steps you think UM could take to ensure that the integrity of your UM work is not compromised by your relationship with the entity. Be thorough. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

In my positions with IHV and Profectus, I will not be involved in the negotiations between UMB with Profectus to establish any terms of commercialization and I will excuse myself from any such discussions in any capacity. Additionally, I will neither advise nor participate in any decision-making in my capacity as a Profectus Scientific Advisory Board member that would affect UMB. I will disclose my interest in Profectus whenever I am presenting or publishing the results of my research.

Have you discussed these suggestions with the entity (y/n)? yes

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)? n/a \_\_\_\_\_

**Section Three. Research and Development Activities.** Explain how, in your view, the exemption will advance the research and development goals of the Public-Private Partnership Act. What are the research and development activities of the entity? In providing this information, remember that the UM Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development define "research" and "development" as basic or applied research or development, including (A) the development or marketing of university-owned technology or intellectual property; (B) the acquisition of services of an official or employee by an entity for research and development purposes; or (c) participation in State economic development programs. Research does not have to be sponsored research in order for relationships with entities to be eligible for Public-Private Partnership Act exemptions.

As per the Commercialization Agreement that created the IHV, Drs. Gallo, Blattner and Redfield were encouraged to establish one or more entities to commercialize products developed at the IHV. Profectus is developing a prophylactic vaccine and a therapeutic for HIV infection around technology developed at the IHV for which it has negotiated license agreements with UMBI and UMB.

**Section Four. Details of Relationship.** Provide information about the entity's relationship, present and/or proposed, with UM, and the entity's present or proposed interest in your work at UM.

As per the Commercialization Agreement Drs. Gallo, Blattner and Redfield have Designated several technologies developed at the IHV to Profectus. UMB and UMBI have negotiated license agreements for these technologies with Profectus. UMBI and UMB have granted licenses to Profectus to make use and sell products developed under the terms of the licenses. I am an inventor on 2 technologies currently licensed to Profectus and I currently perform direct research utilizing these technologies.

A. Sponsored Research Agreements. Describe any present or proposed sponsored research agreements with the entity, as sponsor or as subcontractor to UM, involving you or your laboratory or academic group. Give the approximate budget, the Principal Investigator, the title of the project, and the name of the

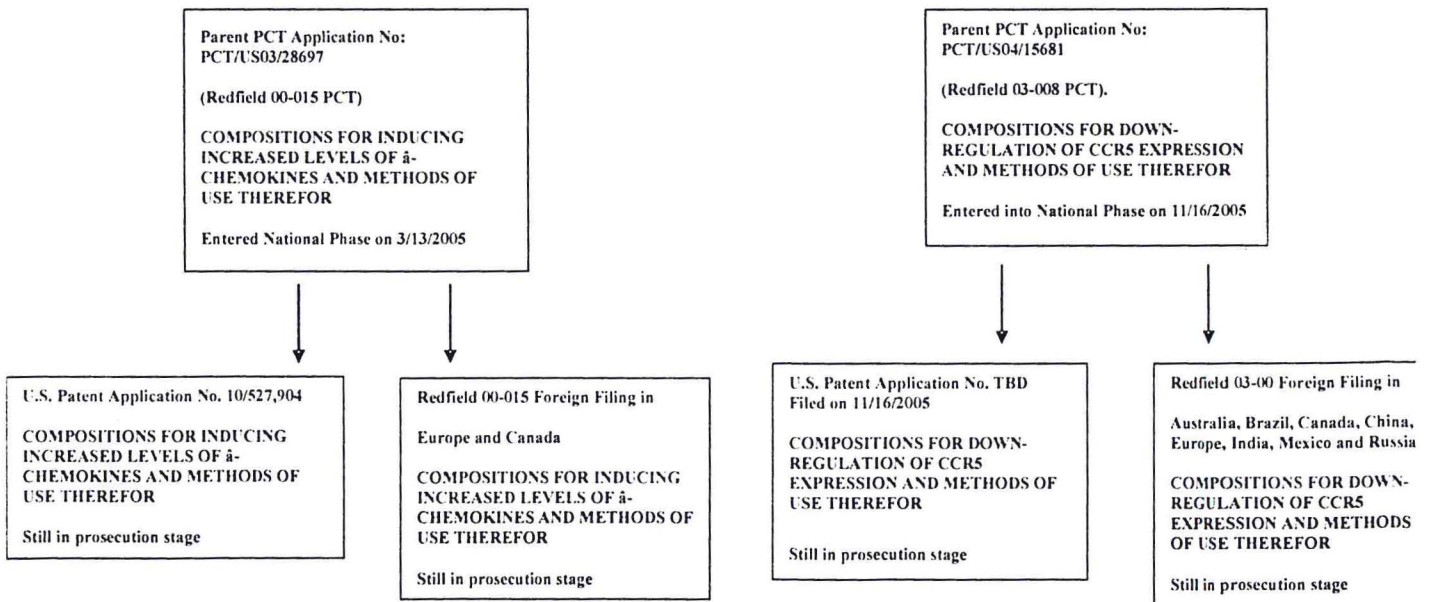
grants and contracts administrator most familiar with the project.

1. **Maryland Industrial Partnership**  
Granted: Feb 1, 2007 for 1 year  
Cholera A1 Subunit as an HIV DNA Vaccine Adjuvant  
Ken Bagley, Profectus/ George Lewis PI, UMBI  
Budget: \$225,622
2. **Maryland Industrial Partnership**  
Granted: August 1, 2006 for 1 year  
Developing Rapamycin to Treat HIV Infection  
Tim Fouts, Profectus/ George Lewis PI, UMBI  
Budget: \$200,000
3. **National Institutes of Health**  
NIAID  
Enhancing DNA Vaccines Using Modified Cholera Like Toxin A1 Subunits and adjuvants  
Tim Fouts, Profectus PI  
Granted: June 1, 2007 for 1 year  
Budget: \$294,643
4. **Gates Foundation**  
Sterilizing Protection Elicited by an HIV-1 Vaccine  
Robert Gallo PI, George Lewis, Co-PI  
Pending  
Request: \$15,000,000

B. Options or License Agreements. Describe any present or proposed options or license agreements known to you between UM and the entity if such agreements relate to inventions or other intellectual property developed by you or in your laboratory or academic group, giving the title of the subject intellectual property.

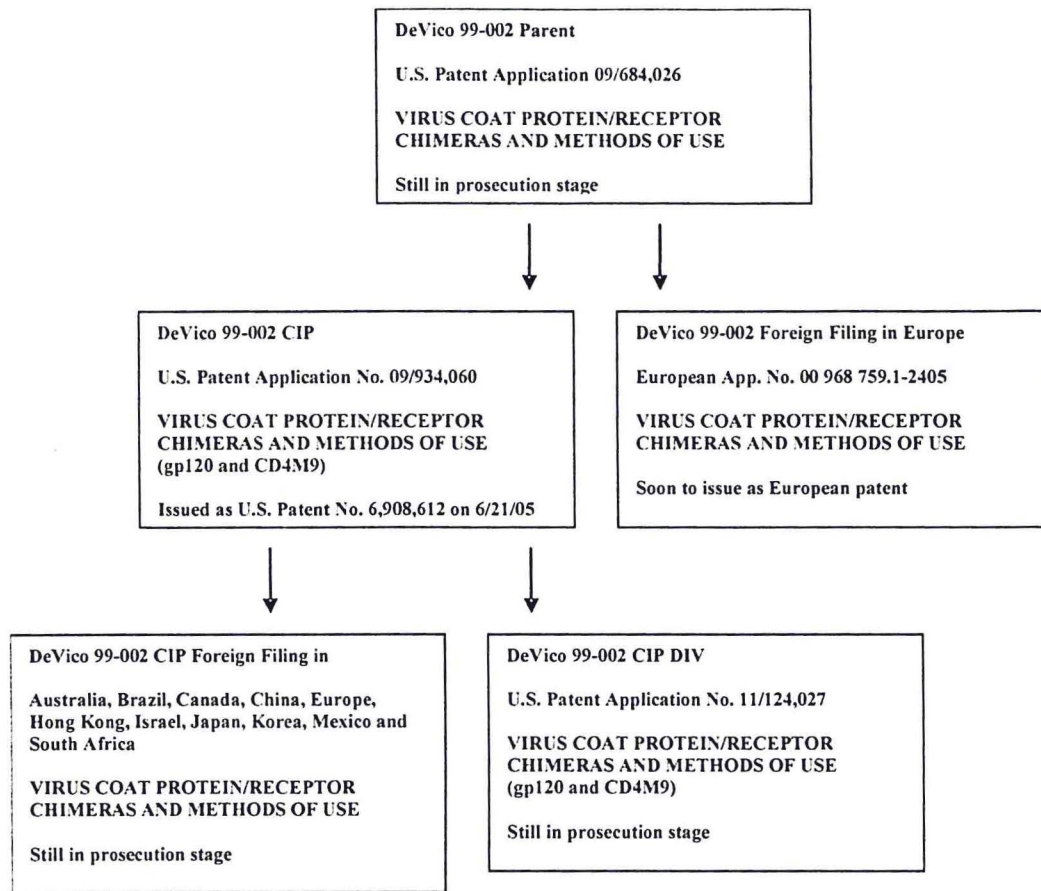
It is my understanding that Profectus has licensed the following technologies from UMBI or UMB:

*Cell Cycle Agents:*

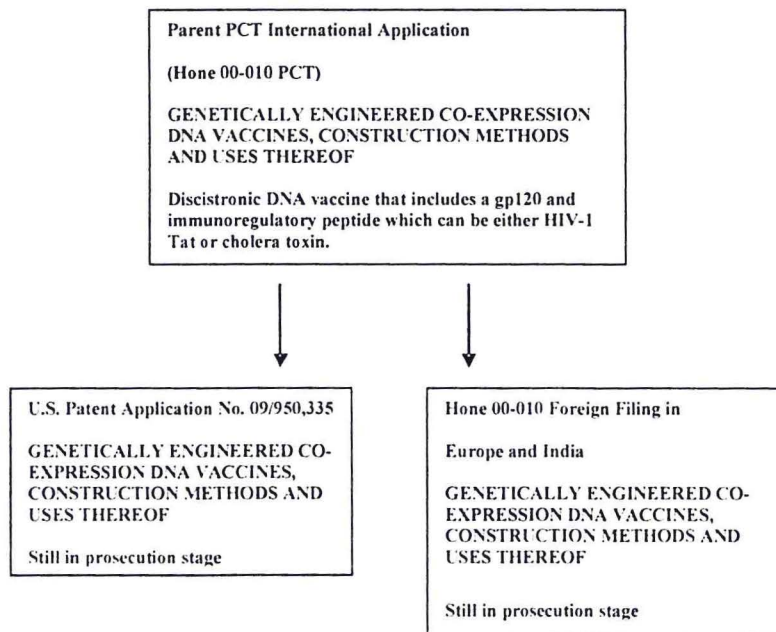




***HIV Vaccine/Viral Entry Inhibitors:***



***Vectored Vaccine Adjuvants:***



C. Entity Interest in Outcome. If, to your knowledge, the entity is interested in the outcome of your research or academic work, but is not a sponsor of your work, explain why the entity has such interest, in your opinion.

D. Gifts or Grants. If the entity has made gifts or grants to UM or the University of Maryland Foundation (UM Fund) in support of your work at UM, give information about the dates and amounts of the gifts or grants, including whether or not the funds were used for any purpose related to your proposed relationship with the entity.

**Section Five. Ownership Information.** If you are requesting an exemption permitting you to have an ownership interest in an entity, provide the requested information, and attach a copy of any written proposal or offer covering the ownership interest.

A. What "units" you will or may own. (E.g., stock, warrants, limited partnership interest, LLC interest.)

B. Ownership.

Individual   X   Joint       

If joint, name of co-owner: \_\_\_\_\_

C. Value of your Ownership Interest. Current estimated dollar value **\$500,000 not discounted for non-liquidity**. Percent of total ownership **2.4% on a fully diluted basis**.

Common shares: 499,970

D. Conditions of Ownership. Describe any conditions or encumbrances affecting your ownership interest. (E.g., will you be prohibited from exercising options or selling stock for a certain period of time, or until certain events occur?)

**Pursuant to a Shareholders Agreement I must first offer any stock I wish to sell to the other Profectus Shareholders. Additionally, the other Profectus Shareholders have a right on a prorated basis to participate in any sale of stock that I make to any other party.**

E. Will you purchase the ownership interest? (Y/N) Y If so, what will you pay for it? \_\_\_\_\_ How does that price compare with the market value, if there is a market value?

**In 2004 I purchased 499,970 shares of Profectus Common for \$.005 per share for a total of \$2498.50. This was the market value as determined by the board of directors of Profectus.**

F. If you are not purchasing the ownership interest, what is the consideration for the ownership interest?

G. From what person or organization will you acquire your ownership interest?

**My common stock was acquired directly from the Company.**

**Section Six. Your Employment Relationship.** If you are requesting an exemption for an employment relationship (including both traditional compensated employment and other relationships e.g., consulting, office or executive responsibility in the entity's operations, board membership, royalties, etc.), attach a copy of any written proposal or offer covering the employment relationship and provide the requested information:

A. What position will you hold? What duties will you have on behalf of the entity? Be as specific as possible. In particular, if you will be conducting any research or scientific work for the entity, address what you will be doing, where you will do it, and the relationship, if any, to your work at UM.

Title: Member of the Profectus Scientific Advisory Board  
Responsibilities:

The Scientific Advisory Board will be charged with advising the board of directors of the Company about setting the overall scientific mission and agenda of the Company and to review current and proposed program areas. My position is one of providing advice to the Company and not one of final decision or policy making for the Company. In my position as a member of the scientific advisory board I may be asked to review research grants submitted by the company including but no limited to grants intended to be submitted to the NIH but it is not intended that I will act as a principal investigator in any grants submitted by the Company at this time.

As described above I have received grant funds to perform research for and with Profectus. The research will be performed in my laboratory and all the costs associated with this research are recovered from the grant funds.

B. How much time per biweekly period \_\_\_\_\_, month \_\_\_\_\_, year \_\_\_\_\_ will you be providing to the entity? \_\_\_\_\_

I anticipate that I will provide services to MBTI one day per month.

C. What compensation, if any, do you expect from the entity?

None

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) Yes \_\_\_\_\_ If no, please explain.

E. Are you requesting a leave of absence or change in level of FTE at UM in order to make your time available to the entity? (Y/N) NO  
If available, attach a copy of the request you have made and the approval.

F. If you are an externally funded investigator, what percentage of your FTE is budgeted to grants and contracts at this time?

70%

---

**Section Seven.** Gifts. Describe any gifts for which you are requesting an exemption because of your relationship with the donating entity, or that entity's interest in your work. **None.**

If you are seeking permission to accept a gift or honorarium from an entity which has a relationship with you, or an interest in your work, provide the nature and value of the gift. You need to give this information whether you are considering a gift directly to you which you plan to retain, a gift you plan to give to another person or entity (e.g., assigning the gift to the UM Fund), or a gift arranged through you but directed to the UM Fund or other UM affiliates which can hold and administer funds for the benefit of your work.

Give the nature and value of the gift (cash, stock, etc.,; market value or face value), and attach a copy of any written offer.

**Section Eight.**

A. Other Relationships with the Entity. Provide information about any other relationship with the entity which has not been discussed above, but which may require an exemption to be lawful. Include here matters such as employment of a spouse or dependent child by the entity, ownership of an interest in the entity by a spouse, dependent child, or other dependent, or relationships between the entity and other organizations with which you or your spouse or dependent child have ownership or employment relationships. In describing ownership interests, give details, including percentage interest and value. In describing employment, give levels of effort and salary.

**None.**

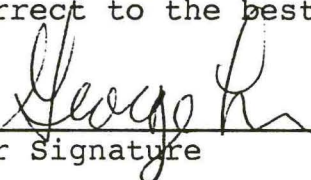
B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption request.

**None.**

**Section Nine.** Signature and Approvals.

Before routing this form, execute it here. Please remind other reviewers to consider this form thoughtfully, complete their sections below, and execute the form if they are forwarding your request with a positive recommendation. Omit any steps of review which are not applicable to you. Be sure the last reviewer forwards the exemption request to the Conflict of Interest Officer.

A. I hereby make oath or affirm that the contents of this Exemption Request are true and correct to the best of my knowledge, information and belief.

  
\_\_\_\_\_  
Your Signature

6-29-07  
\_\_\_\_\_

Date




**UNIVERSITY OF MARYLAND**  
Office of the President

DAVID J. RAMSAY, DM, DPhil  
President

520 West Lombard Street  
Baltimore, Maryland 21201-1627  
410 706 7002 | 410 706 0500 FAX

**MEMORANDUM**

TO: Stephen Gottlieb, M.D.  
Professor  
Division of Cardiology  
Department of Medicine  
School of Medicine

FROM: David J. Ramsay, D.M., D.Phil.  
President 

RE: Conflict of Interest Disclosure #03-08-001  
Biogen Idec

DATE: March 24, 2008

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated March 11, 2008, involving consulting services, and a research agreement with, Biogen Idec, as described in your exemption request. Your association with Biogen Idec will facilitate research and development. I have determined that your relationship with Biogen Idec would not be a harmful interest, as described in the USM Board of Regents' Policy on Conflicts of Interest in Research and Development. This exemption permits your association with Biogen Idec as described in your exemption request. In the absence of this exemption, your association with Biogen Idec would conflict with Maryland Public Ethics Law, and with USM and UMB policy.

The conditions of this exemption follow:

- Your business and financial relationship with Biogen Idec must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and subjects) participating in your Biogen Idec funded research or related research. Your relationship with Biogen Idec must also be disclosed when you publish or speak on the Research. While this latter requirement is already standard with most professional journals and scientific meetings, in the interest of mitigating your conflicts, it must also be applied to presentations made on campus.

- Information about your research plans and outcomes must not be disclosed to Biogen Idec prior to the time that such information is made available to the scientific community as a result of publication, except as specified in any research, licensing, material transfer or other agreements between the University and Biogen Idec or except as necessary to the development of collaborative research proposals involving the University and Biogen Idec
- All of the research you propose, all of the findings that result from or affect your Biogen Idec activities, and the conflict of interest issues surrounding your Biogen Idec relationship must be disclosed to and discussed with your Department Chair on a regular basis to ensure the integrity of the science proposed and the publications prepared. Your discussions should be documented by you in writing and include an implementation plan for any changes suggested by your Department Chair. Copies of this documentation must be promptly submitted to the School of Medicine Dean's Office and the UMB Conflict of Interest Officer. These requirements are intended to diminish any perception that your research plans, results or publications may be biased as a result of your relationship with Biogen Idec
- If graduate students or postdoctoral fellows join your laboratory to conduct research sponsored by Biogen Idec under your direction and mentorship, it will be necessary for a faculty member uninvolved with your academic division or research to monitor the student's academic progress and research work and publications to assure that your financial interests in Biogen Idec do not adversely affect the student's academic needs. Your Department Chair will be responsible for identifying the faculty monitor and assuring that this provision is met.
- It is assumed that your Biogen Idec-sponsored research activities are related to your consulting activities only as described in the disclosure documentation you provided, and that mechanisms for ensuring the integrity of the research (including its design and conduct, and the collection, analysis and reporting of data) are in place. Further, it is assumed that any other University research activities undertaken by you are unrelated to your consulting activities for Biogen Idec. You must inform the Conflict of Interest Officer and your Department Chair immediately if these assumptions are incorrect or the facts change. Your consulting activities for Biogen Idec shall not involve the use of University funds or facilities, or personnel other than yourself, as described.
- All research personnel and activities in your laboratory must be supported according to their level of effort and use, respectively, on various projects, supported by the standard departmental review and approval of related documentation (such as University Grant Routing Forms and Time and Effort Reports). Biogen Idec must pay full compensation for the time of personnel and for other research costs, and must pay full facilities and administrative costs unless waivers or reductions have been approved in accordance with University policy.

- You file timely annual reports with the Conflict of Interest Officer.

Note that this exemption may be voided by me in the event of your failure to satisfy all of the foregoing conditions. Procedural questions regarding this exemption should be directed to the UM Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

This exemption permits your association with Biogen Idec in a manner that comports with the requirements of the Maryland Public Ethics Law and University policy, provided that the conditions of the exemption are observed. Any significant change in your planned relationship with Biogen Idec, as disclosed in your exemption request, must be promptly disclosed to the University (through your Department Chair and Dean), so that the effect of the change in circumstances may be determined. I recommend you disclose and discuss proposed changes prospectively to avoid potential withdrawal of this exemption.

PC: Frank Calia, M.D.  
Joseph Giffels, M.A.S.  
James Hughes, M.B.A.  
Malinda Orlin, Ph.D.  
E. Albert Reece, M.D., Ph.D., M.B.A.



EXEMPTION REQUEST FORM  
DISCLOSING CONFLICT OF INTEREST  
RELATED TO RESEARCH OR DEVELOPMENT

PART TWO:

DISCLOSURE AND EXEMPTION REQUEST

Please provide all information in boldface type.

Section One. Directory Information. Supply the requested information about yourself, as the employee requesting the exemption, and about the entity with which your relationship is proposed:

A. About You

Name: Stephen Gottlieb, M.D.

University Title: Professor

Division/Department or Administrative Unit: Cardiology/Medicine

FTE: fulltime Annual Salary: 227,000

University Business Address: Room S3B08, 22 S. Greene St

Phone Number: 410-328-8788

Facsimile: 410-328-1048

E-mail Address: sgottlie@medicine.umaryland.edu

B. About Your Immediate Supervisor

Name: Mandeep Mehra, M.D.

University Title: Head, Divison of Cardiology

University Business Address: Room S3B06, 22 S. Greene St

Phone Number: 410-328-7716

Facsimile: 410-328-4382

E-mail Address: mmehra@medicine.umaryland.edu

C. About the Entity

Name: Biogen Idec

Form of Organization: Corporation  
(e.g., LLC, corporation, partnership)

State in which it is organized: Delaware

General nature of its business activities: Pharmaceutical Company

Any other names under which it does business, and the names of any wholly owned subsidiaries, or corporate parents (companies which own the entity) which conduct business similar to the entity's business, or which also have relationships with UM or you. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

A Contact Person: Give the name and title of an officer or other person at the entity or its parent who is informed about the proposed relationship:

Dr. Aaron Deykin, Associate Director, Medical Research, Immunology and Inflammation, Biogen Idec, Inc.

Give the person's business address: 14 Cambridge Center  
Cambridge, MA 02142

Telephone Number: 617-679-2155

Facsimile Number: 617-679-3518

E-Mail Address: aaron.deykin@biogenidec.com

D. Additional Information

Is the entity an ongoing business concern?  yes  no

If the entity is to be established, (a) when do you think it will be created? \_\_\_\_\_ (give month and year)

(b) What state will it be organized in? \_\_\_\_\_

Section Two. Your Conflict of Interest Concerns. Supply information about the potential or actual conflict of interest and your proposal to mitigate it.

A. Description of Conflict of Interest. Describe in your own words the potential or actual conflict of interest which you or others have identified which led you to file this exemption request. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

I have been hired as a consultant, both to be on the steering committee of a study in which I am local PI of a multicenter study, and to consult with the company about development of the drug. That is, in addition to discussing the Biogen (oral BG9928 phase 2) trial, I may be involved in discussions of other trials that should be performed. Total compensation will be less than \$10,000/year.

B. Steps to Mitigate Conflict. Describe in your own words what steps you think UM could take to ensure that the integrity of your UM work is not compromised by your relationship with the entity. Be thorough. Use the space provided, or attach a statement. You may attach supporting documents as helpful.

As a PI of one site of a blinded multicenter trial with hundreds of sites, I have minimal ability to impact the results of the study. Thus, the potential COI has little chance of affecting the outcomes of the study.

My financial relationship with the company will be disclosed whenever I speak or publish on Biogen Idec, Inc.-sponsored research or on topics related to this research.

Have you discussed these suggestions with the entity (y/n)? NA

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)? NA

Section Three. Research and Development Activities. Explain how, in your view, the exemption will advance the research and development goals of the Public-Private Partnership Act. What are the research and development activities of the entity? In providing this information, remember that the UM Procedures Implementing Board of Regents Policy on Conflicts of Interest in Research or Development define "research" and "development" as basic or applied research or development, including (A) the development or marketing of university-owned technology or intellectual property; (B) the acquisition of services of an official or employee by an entity for research and development purposes; or (c) participation in State economic development programs. Research does not have to be sponsored research

in order for relationships with entities to be eligible for Public-Private Partnership Act exemptions.

We have worked with Biogen-Idec to develop this class of agents, starting with initial phase 2 studies and the first clinical publication about an adenosine A1 antagonist in heart failure. We are seen internationally as leading experts on adenosine antagonists, which has led to many studies of these agents at UMD and should lead to more to both us and other investigators at the University of Maryland.

Section Four. Details of Relationship. Provide information about the entity's relationship, present and/or proposed, with UM, and the entity's present or proposed interest in your work at UM.

A. Sponsored Research Agreements. Describe any present or proposed sponsored research agreements with the entity, as sponsor or as subcontractor to UM, involving you or your laboratory or academic group. Give the approximate budget, the Principal Investigator, the title of the project, and the name of the UM grants and contracts administrator most familiar with the project.

I am local PI of a study entitled "A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Tolerability of Oral BG9928 in Patients with Heart Failure and Renal Insufficiency" Center for Clinical Trials/ Senior Contract Administrator: Cathleen Smith.

B. Options or License Agreements. Describe any present or proposed options or license agreements known to you between UM and the entity if such agreements relate to inventions or other intellectual property developed by you or in your laboratory or academic group, giving the title of the subject intellectual property.

NA

C. Entity Interest in Outcome. If, to your knowledge, the entity is interested in the outcome of your research or academic work, but is not a sponsor of your work, explain why the entity has such interest, in your opinion.

NA

D. Gifts or Grants. If the entity has made gifts or grants to UM or the University of Maryland Foundation (UM Fund) in support of your work at UM, give information about the dates and amounts of the gifts

or grants, including whether or not the funds were used for any purpose related to your proposed relationship with the entity.

NA

Section Five. Ownership Information. If you are requesting an exemption permitting you to have an ownership interest in an entity, provide the requested information, and attach a copy of any written proposal or offer covering the ownership interest.

A. What "units" you will or may own. (E.g., stock, warrants, limited partnership interest, LLC interest.)

NA

B. Ownership.

Individual \_\_\_\_\_ Joint \_\_\_\_\_

If joint, name of co-owner: \_\_\_\_\_

C. Value of your Ownership Interest. Current estimated dollar value \_\_\_\_\_ . Percent of total ownership \_\_\_\_\_ .

D. Conditions of Ownership. Describe any conditions or encumbrances affecting your ownership interest. (E.g., will you be prohibited from exercising options or selling stock for a certain period of time, or until certain events occur?)

NA

E. Will you purchase the ownership interest? (Y/N) \_\_\_\_ If so, what will you pay for it? \_\_\_\_\_ How does that price compare with the market value, if there is a market value?

F. If you are not purchasing the ownership interest, what is the consideration for the ownership interest?

NA

G. From what person or organization will you acquire your ownership interest?

NA

Section Six. Your Employment Relationship. If you are requesting an exemption for an employment relationship (including both traditional compensated employment and other relationships e.g., consulting,

office or executive responsibility in the entity's operations, board membership, royalties, etc.), attach a copy of any written proposal or offer covering the employment relationship and provide the requested information: NA

A. What position will you hold? What duties will you have on behalf of the entity? Be as specific as possible. In particular, if you will be conducting any research or scientific work for the entity, address what you will be doing, where you will do it, and the relationship, if any, to your work at UM.

Title: Consultant

Responsibilities: Advising about the best means of ensuring successful and appropriate implementation of the Biogen BG9928 trial and advising about other studies which should be performed.

B. How much time per biweekly period \_\_\_\_\_, month \_\_\_\_\_, year \_\_\_\_\_ will you be providing to the entity? not more than 4 days per year

C. What compensation, if any, do you expect from the entity?

\_\_\_\_\_ <\$10,000 annually\_\_\_\_\_

D. Will you use annual and other paid leave time for the work for the entity? (Yes) \_\_\_\_\_ If no, please explain.

E. Are you requesting a leave of absence or change in level of FTE at UM in order to make your time available to the entity? (Y/N) \_\_\_\_\_ If available, attach a copy of the request you have made and the approval.

F. If you are an externally funded investigator, what percentage of your FTE is budgeted to grants and contracts at this time?

\_\_\_\_\_ 15%\_\_\_\_\_

Section Seven. Gifts. Describe any gifts for which you are requesting an exemption because of your relationship with the donating entity, or that entity's interest in your work.

If you are seeking permission to accept a gift or honorarium from an entity which has a relationship with you, or an interest in your work, provide the nature and value of the gift. You need to give this information whether you are considering a gift directly to you which you plan to retain, a gift you plan to give to another person or entity (e.g., assigning the gift to the UM Fund), or a gift arranged through you but directed to the UM Fund or other UM affiliates which can hold and administer funds for the benefit of your work.

Give the nature and value of the gift (cash, stock, etc.; market value or face value), and attach a copy of any written offer.

NA

Section Eight.

A. Other Relationships with the Entity. Provide information about any other relationship with the entity which has not been discussed above, but which may require an exemption to be lawful. Include here matters such as employment of a spouse or dependent child by the entity, ownership of an interest in the entity by a spouse, dependent child, or other dependent, or relationships between the entity and other organizations with which you or your spouse or dependent child have ownership or employment relationships. In describing ownership interests, give details, including percentage interest and value. In describing employment, give levels of effort and salary.

NA


B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption request.

NA

Section Nine. Signature and Approvals.

Before routing this form, execute it here. Please remind other reviewers to consider this form thoughtfully, complete their sections below, and execute the form if they are forwarding your request with a positive recommendation. Omit any steps of review which are not applicable to you. Be sure the last reviewer forwards the exemption request to the Conflict of Interest Officer.

A. I hereby make oath or affirm that the contents of this Exemption Request are true and correct to the best of my knowledge, information and belief.

  
Your Signature

11/31/08  
Date

B. Supervisor's Statement



UNIVERSITY OF MARYLAND  
SCHOOL OF MEDICINE  
CARDIOMYOPATHY AND PULMONARY HYPERTENSION PROGRAM

Re: Conflict of Interest Disclosure for Biogen Idec

I hereby make oath or affirm that the contents of this Exemption Request are true and correct to the best of my knowledge, information and belief. I have reviewed my research and financial interests with my Department Chair and we have discussed the resulting conflicts of interest. I will take all necessary measures to minimize any actual or perceived clinical or scientific bias which may result from these conflicts of interest, including abiding by all conditions upon which an exemption may be granted. Further, I will discuss any new development or change in my current situation with my Department Chair and determine what, if any, additional measures must be taken to minimize any effects of my financial interests.

Steph Gottlieb  
Your Signature

2/28/08  
Date

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Date

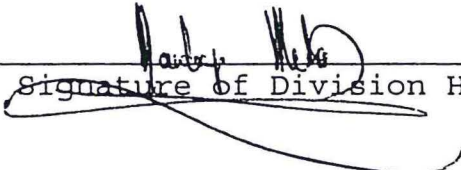
\_\_\_\_\_  
Supervisor's Signature

C. Statement of Division Head or Director

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2/5/08  
Date

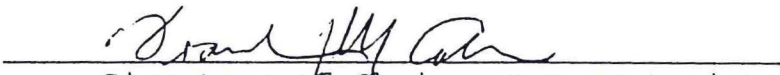
  
Signature of Division Head or Director

D. Statement of Chairperson or Assistant/Associate Vice President

I have reviewed this exemption request and I support it, subject to the conditions, if any, set out here: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2/15/08  
Date

  
Signature of Chairperson or Assistant/  
Associate Vice President

E. Statement of Vice Dean for Research and Academic Affairs

I have reviewed this exemption request. I am aware of the nature of the conflict and the proposed measures to mitigate it. I am forwarding it to the Conflict of Interest Advisory Committee for its review, comments and suggestions.

*Bruce E. Jandy*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Vice Dean

F. Statement of Dean

I have reviewed this exemption request. I am aware of the nature of the conflict and the proposed measures to mitigate it. I am forwarding it to the Conflict of Interest Advisory Committee for its review, comments and suggestions.

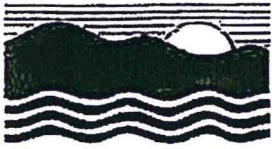
*3/11/08*

\_\_\_\_\_  
Date

*F. Abbott Lee*

\_\_\_\_\_  
Signature of Dean

FORWARD THIS FORM VIA CAMPUS MAIL TO J. JOSEPH GIFFELS, UMB CONFLICT OF INTEREST OFFICER, ACADEMIC AFFAIRS, FOURTH FLOOR, PACA-PRATT BUILDING.



University of Maryland  
CENTER FOR ENVIRONMENTAL SCIENCE

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MEMORANDUM

**To:** Dr. Donald Boesch  
President

**From:** Dr. Mark S. Castro *Mark S Castro*  
Chair, COI Committee

**Date:** February 4, 2008

**Subject:** Conflict of Interest Disclosure for Vincent M. Kelly - #08-01

In accordance with UMCES Policies and Procedures on Conflict of Interest (COI) and Commitment, the President's Conflict of Interest committee has reviewed the COI disclosure from Vincent M. Kelly. Our recommendation is described below for your review and determination.

COI Committee Meeting

The COI committee currently consists of Drs. Castro and Harvey and Ms. Erica Kropp, Interim Vice President for Administration. This committee conducted a conference call Thursday, January 31, 2008 to review the COI disclosure for Vincent M. Kelly #08-01. After much discussion, the committee reached a unanimous decision, which was summarized by Ms. Kropp. This summary, which is presented here, was subsequently reviewed, edited and approved by the COI committee.

Conflict

Vincent M. Kelly, a part-time (49%) UMCES Faculty Research Assistant with the Horn Point Laboratory (HPL) is also the owner of Green Eyes LLC, a small start-up company located in Easton, MD. Green Eyes LLC wants to rent and occupy laboratory space at HPL, in Cambridge, MD.

Disclosure Summary

Until mid 2007, UMCES was preparing to build and manage a business incubator at HPL. Green Eyes LLC is one of the companies that had been slated to occupy this incubator. This business incubator is now going to be built at the Cambridge Airport by Dorchester County, and is not expected to be open for two or more years. HPL has agreed to be an interim provider of space for selected start-up companies. Green Eyes LLC wants to enter into a lease agreement with UMCES until the County incubator is ready for occupancy.

Conditions for Approval

The COI committee supports the conflict management plan proposed by Mr. Kelly with the additional conditions that the lease be for no more than three years and would contain terms to indicate that the lease could terminate before the end of the three years, if (1) the Dorchester County business incubator is ready for occupancy or, (2) if the space rented by Green Eyes LLC at HPL is needed for faculty research or other laboratory business as determined by the HPL laboratory director.





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Recommendation

The COI committee has concluded that the disclosed conflict, managed with the conditions above, does not constitute a harmful interest, and recommends that this disclosure be approved for exemption from the provisions of the State of Maryland Public Ethics Law.

Please indicate (below) whether or not you approve our recommendation. Please return your recommendation to the COI Administrator, Ms. Erica Kropp, and we will notify the faculty member and other appropriate parties of your determination. As required, any exemptions granted will also be reported to the Maryland State Ethics Commission and the Chancellor for the UMS.

Approve of COI Committee recommendation:

Yes

No

*Donald J. Boesch*

*2-7-2008*

Signature: UMCES President Boesch

Date

Attachments:

- Kelly Disclosure
- HPL Letter
- Kelly Letter

