



OFFICE OF THE CHANCELLOR

February 14, 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 December 31, 2007, exemptions were granted by the University of Maryland, Baltimore, 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,

A handwritten signature in black ink that reads "WE Kirwan".

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

1898
Frostburg 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



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

RECEIVED

JAN 11 2008

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

CHANCELLOR'S OFFICE

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

DATE: January 8, 2008

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

There were 4 exemptions granted to UMB personnel between October 1 and December 31, 2007 pursuant to the Public-Private Partnership Act.

Supporting documentation is enclosed.

EMPLOYEE	INTEREST	ENTITY	DATE OF EXEMPTION
Scott Strome, M.D.	Equity, Inventor	Gliknik	11/14/07
Timm Dickfeld, M.D., Ph.D.	Consultant	Biosense Webster	12/03/07
Hoag, Stephen, Ph.D.	Equity, Inventor	InfraTrac, Inc.	12/20/07
James Polli, Ph.D.	Equity, Inventor	InfraTrac, Inc.	12/20/07

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: Scott Strome, MD
Professor and Chairman
Department of Otorhinolaryngology – Head and Neck Surgery
School of Medicine

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

RE: Conflict of Interest Disclosure #11-07-011

DATE: November 14, 2007

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated August 9, 2007. Your request involves proposed relationships between you and Gliknik. You propose service on Gliknik's Scientific Advisory Board, ownership of equity in Gliknik, and a personal consulting agreement with Gliknik. In addition, Gliknik is anticipated to license technologies you invented and which are owned by the University of Maryland Baltimore (UMB) and the Mayo Clinic and, as an inventor, you stand to receive a share of institutional royalties as a result of those licenses.

These proposed relationships present a conflict of interest because you plan to participate as a UMB investigator on research of interest to Gliknik.

I find that your association with Gliknik will facilitate research and development. I have determined that your relationship with Gliknik 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 Gliknik as described in your exemption request. In the absence of this Exemption, your association with Gliknik would conflict with the Maryland Public Ethics Law, as well as University System of Maryland and UMB policy.

The conditions of this Exemption follow:

- All of your business and financial relationships with Gliknik 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 Gliknik is a research sponsor, and whether or not it is directly involved in the research. Your relationships with Gliknik 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 Gliknik relationships to enable an understanding of the significance of the relevant financial relationships. UMB will review the disclosure plan annually. 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 Gliknik. A principal investigator, a qualified scientist, must be identified who does not report directly to you 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 meet 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, 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 Gliknik'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 Gliknik is approved, however. You must recuse yourself from participating in the making of decisions involving UMB, including the consideration of issues involving University of Maryland technologies.

- Faculty, staff and trainees (graduate students and postdoctoral fellows) in Otorhinolaryngology-Head and Neck Surgery shall all receive notice that the Office of the Vice President for Academic Affairs 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.
- Your consulting activities for Gliknik shall not involve the use of UMB funds or facilities, or personnel other than yourself, as described.
- You and all of the research personnel and activities in your laboratory must be supported according to their level of effort and use, respectively, on various projects and subjected to the standard Departmental and School review and approval of related documentation (such as UMB Grant Routing Forms and Time and Effort Reports).
- Your share of equity interest (including equity interests of your family members, if any) in Gliknik 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 Gliknik must be held by you until the earliest of the following trigger events:

- upon arms-length acquisition of all the stock or assets of Gliknik 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.
 - As you are an Investigator on an NIH-sponsored research grant, 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.

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.

This Exemption permits your association with Gliknik 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 Gliknik, 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.

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: **Scott Strome**

University Title: **Professor and Chairman, Department of OTO-HNS**

Division/Department or Administrative Unit: **OTO-HNS**

FTE: **1** Annual Salary: **__\$510,306_____**

University Business Address: **16 South Eutaw St. Baltimore, Md**

Phone Number: **(410) 328 6467**

Facsimile: **(410) 328 6192**

E-mail Address: **SSTROME@SMAIL.UMARYLAND.EDU**

B. About Your Immediate Supervisor

Name: **Albert E Reece**

University Title: **Dean of the School of Medicine**

University Business Address: **Office of the Dean, 14th floor
Bressler Research Building, 655 W. Baltimore St., Baltimore, Md**

Phone Number: **(410) 706 7410**

Facsimile: **(410) 706 0235**

E-mail Address: **deanmed.som.umaryland.edu**

C. About the Entity

Name: **Gliknik**

Form of Organization: **_____C corporation_____**
(e.g., LLC, corporation, partnership)

State in which it is organized: Delaware

General nature of its business activities: **Biotechnology 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. **None**

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:
David Block, MD

Give the person's business address: 2006 Skyline Road, Ruxton, MD 21204

Telephone Number: 410-963-3959
Facsimile Number: 410-828-9031
E-Mail Address: **dblock@Gliknik.com**

D. Additional Information

Is the entity an ongoing business concern? xyes ___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.

1. 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 one of two owners of a recently-formed company, Gliknik. Gliknik has been organized to develop and market technologies and products associated with scientific and medical immunology.

In addition to being an owner, I anticipate being a compensated member of Gliknik's Scientific Advisory Board and, in addition, to devote approximately 5% of my effort to administrative and business matters associated with Gliknik.

Finally, it is anticipated that Gliknik will license technologies which I co-invented while at the Mayo Clinic and UMB. Licenses between Mayo and UMB and Gliknik are anticipated to yield fees and royalties in which I will share by virtue of having been an inventor while employed at Mayo and UMB.

At the same time, I am directing research involving the technologies and products being licensed to Gliknik. These research projects are now, or are anticipated to be, funded by the NIH, the School of medicine, philanthropy, Gliknik and the State of Maryland's Maryland Industrial Partnerships (MIPS) program.

Because my financial relationships with Gliknik and/or my personal financial interest in the development and marketing of the technologies I co-invented may be affected by the outcome of research I will be directing, it may be perceived that the research may be biased in its design, conduct or reporting.

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.

My intent in developing a plan to mitigate this conflict of interest is three fold. First, because I am Chairman of the Department of Oto-HNS and control the departmental budget, I want to ensure that there is an appropriate structure in place to oversee fund allocations to my laboratory. Second, because I may benefit financially from the results of our studies, the overall mitigation plan needs to include research oversight. Third, because I mentor students, residents, post-doctoral fellows and faculty in my laboratory, the conflict resolution plan needs to entail a mechanism to ensure preservation of the overall academic mission of my research program. In order to facilitate review, I will address each of these issues individually.

As Chairman of the Department of OTO-HNS, I am responsible for both the research and clinical budgets. Our laboratory is funded by multiple sources including the NIH, cigarette restitution dollars, philanthropy, the University of Maryland SOM, and FAMRI. I take pride in the fact that the research performed in our laboratory is truly collaborative and projects are often shared. The laboratory is designed to support this collaborative effort, with capital equipment and common supplies viewed as shared resources, and a smaller subset of reagents purchased specifically for individual projects. In order that Gliknik participate in this process, I propose the following:

1. Reagents purchased specifically for projects being funded under the Sponsored Research Agreement by Gliknik will be billed to the company. Specific projects intended for inclusion are defined in appendix A.

2. Gliknik will help provide salary support to select laboratory personnel. It should be noted that these individuals are staff personnel currently working in my laboratory, so Gliknik support will help offset existing support. Because the products licensed by Gliknik directly relate to my ongoing research, graduate or post-doctoral students may work directly on projects funded by Gliknik. I believe that the integration of students into this academic corporate partnership is of incredible educational potential particularly for the training of translational researchers who, by definition, will work closely with Pharma during their careers.

3. Under the Sponsored Research Agreement, Gliknik may be asked to make a defined contribution to general laboratory funds. These funds will be directed toward the purchase of common supplies e.g. media, shared antibodies etc. and for maintenance fees on shared equipment e.g. flow cytometer, hoods etc.

4. Some of the projects ongoing in my laboratory, which Gliknik may/will license, are funded by other mechanisms. For example, my peptide vaccine trial is funded by an NIH R01. Similarly, Dimeric antibody constructs are being developed by Dr. Sewell with my mentorship. Specific company related projects and proposed funding mechanisms are defined in appendix A.

5. Because of the complicated interplay between the projects which are ongoing in my laboratory and the various mechanisms of support, I believe the most essential component of the plan is transparency. In order to ensure that this occurs, I request that the finances should be reviewed at least quarterly by one of the vice deans, so that any concerns can be addressed in a forthright and timely fashion. This meeting should include our senior departmental administrator, laboratory manager and any additional individuals that the school feels are appropriate. I am willing to be present if it is deemed appropriate.

The second component of the plan needs to include a mechanism to ensure the scientific integrity of the project. This is critical for both the company and me personally. I would recommend the following steps:

1. A senior scientist familiar with immunology to review our raw data and speak directly with my laboratory technicians and post doctoral fellows. They are welcome to review all data and make suggestions regarding experimental design. They are also welcome to review all publications and submissions.

The Third component of the plan must ensure that the academic component of the laboratory is not compromised by this relationship. Importantly, because we do translational research, it is my hope that we can incorporate an understanding of this corporate academic partnership as part of our educational mission. To ensure that the academic nature of the laboratory is maintained, I would recommend:

1. Appointment of an ombudsman to whom any of my technicians, fellows or faculty can report a grievance without fear of retaliation.

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)? Yes

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.

The research in my laboratory is primarily translational - designed to develop novel treatment strategies to help ameliorate human disease. While the costs associated with preclinical translational projects can often be paid through grants, philanthropy and other seed funds, the dollars required to bring a product to the clinic are difficult to fund. This gap between preclinical work and clinical translation is where, in my view, academic industrial partnerships are most valuable. The purpose of Gliknik is to support the clinical translation of ongoing research in my laboratory, truly linking the bench to the bedside.

An exemption would allow this research to continue at UMB and would make my clinical and scientific expertise in this field available to Gliknik.

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.

Gliknik and UMB currently have a sponsored research agreement in place. This agreement pays for approximately 1/4 of a technician's salary in my laboratory. This will increase because of a MIPS grant for which we just received notice of approval which is the subject of both MIPS and Gliknik funding. It may further increase to accommodate support of other projects under an expanded Sponsored Research Agreement in the near future. I am the principal investigator on all the projects. The grants and contracts administrator most familiar is Elizabeth Hart-wells.

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.

Four licensing agreements are anticipated. The first involves peptide technologies, the second involves Fc dimer technologies, the third involves the attachment of Fc multimers to FAb constructs and the fourth involves a chemoenzymatic method to modify glycosylation. Terms of these licensing agreements are being negotiated by UMB with David Block of Gliknik.

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. **N/A**

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. **None**

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.) **I have been issued Founders Stock in Gliknik for which I paid par value.**

B. Ownership.

Individual Joint

If joint, name of co-owner: _____

C. Value of your Ownership Interest. Current estimated dollar value \$75. Percent of total ownership **49.97%** - **this is expected to decrease upon the issuance to UMB of equity in the company under a licensing agreement and further upon the issuance of shares to other investors in August. By September 1, I expect to have a direct equity percentage ownership of about 22.5% and an indirect equity percentage ownership through UMB of about 10.5% for a total of about 33%.**

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?) **There is no market for selling the Gliknik shares. I expect that as part of near-term financing arrangements, I will be required to escrow my ownership shares for a period of approximately 3 years.**

E. Will you purchase the ownership interest? (Y/N) Y If so, what will you pay for it? I paid \$75 - \$0.0001/share How does that price compare with the market value, if there is a market value?

There is currently no market value.

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

N/A

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

Gliknik

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: **Consultant**

Responsibilities: **Not yet determined. I may receive personal cash compensation as a consultant/scientific advisory board member, but these arrangements are not yet in place.**

B. How much time per biweekly period _____, month _____, year _____ will you be providing to the entity? **Approximately 5%**

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

I may receive compensation as a member of the scientific advisory board.

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) N If no, please explain. I am requesting 5% effort for company related activities.

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?
16% (10% MAGE, 5% GTC, 1% MIPS)

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.

None

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.

My parents will purchase stock in the series S round

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. I have reviewed my research and financial interests with Joe Giffels 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 Joe Giffels and determine what, if any, additional measures must be taken to minimize any effects of my financial interests.



Your Signature

Date

8/7/07

B. Supervisor's Statement

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: _____

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: _____

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.

11/29/07
Date

Bruce Z. [Signature]
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.

11/29/07
Date

[Signature]
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.



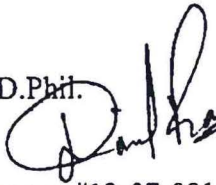
UNIVERSITY OF MARYLAND
Office of the President

DAVID J. RAMSAY, DM, DPhil
President

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

MEMORANDUM

TO: Timm Dickfeld, M.D., Ph.D.
Assistant Professor
Division of Cardiology
Department of Medicine
School of Medicine

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

RE: Conflict of Interest Disclosure #12-07-001
Biosense Webster

DATE: December 3, 2007

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated October 18, 2007 involving consulting services and a research agreement with Biosense Webster, as described in your exemption request. Your association with Biosense Webster will facilitate research and development. I have determined that your relationship with Biosense Webster 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 Biosense Webster as described in your exemption request. In the absence of this exemption, your association with Biosense Webster would conflict with Maryland law, including, but not limited to, Sections 15-504 and 15-507 of the Maryland Public Ethics Law and University policy.

The conditions of this exemption follow:

- Your business and financial relationship with Biosense Webster must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and subjects) participating in your Biosense Webster funded research or related research. Your relationship with Biosense Webster 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 Biosense Webster 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 Biosense Webster or except as necessary to the development of collaborative research proposals involving the University and Biosense Webster.
- All of the research you propose, all of the findings that result from or affect your Biosense Webster activities, and the conflict of interest issues surrounding your Biosense Webster 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 Biosense Webster.
- If graduate students or postdoctoral fellows in your laboratory conduct research sponsored by Biosense Webster 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 Biosense Webster 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 Biosense Webster-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 Biosense Webster. 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 Biosense Webster 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). Biosense Webster 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 Biosense Webster 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 Biosense Webster, 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: Dr. F. Calia
Mr. J. Giffels
Mr. J. Hughes
Dr. M. Orlin
Dean 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: **Timm Dickfeld**

University Title: **Assistant Professor**

Division/Department or Administrative Unit:
Cardiology

FTE: **1.0** Annual Salary: **INFORMATION ON FILE**

University Business Address: **Division of Cardiology, 22 S. South Greene Str, Room N3W77, Baltimore, MD 21201-1595**

Phone Number: **410 328 6056**

Facsimile: **410 328 2062**

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

B. About Your Immediate Supervisor

Name: **Stephen Shorofsky**

University Title: **Professor of Medicine**

University Business Address: **Division of Cardiology, 22 S. South Greene Str, Room N3W77, Baltimore, MD 21201-1595**

Phone Number: **410 328 6056**

Facsimile: 410 328 2062

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

C. About the Entity

Name: Biosense Webster

Form of Organization: Part of Johnson&Johnson
(e.g., LLC, corporation, partnership)

State in which it is organized: _____

General nature of its business activities:
Electrophysiological Mapping

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.
Part of Johnson&Johnson

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:
Ronnie Abbo

Give the person's business address: 4 Etgar St, Tirat Carmel, Israel

Telephone Number: +972 4 8131143

Facsimile Number: +972 4 8131112

E-Mail Address: rabbo@bwiil.jnj.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. Please attach supporting documents.

I am the Principal Investigator of clinical studies which are financially supported by Biosense. With this contract I will also become a paid consultant for Biosense. My financial interests as a consultant may be perceived as a source of bias in the design, conduct or reporting of my research involving Biosense.

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.

My financial interests will be disclosed whenever I speak or publish on Biosense-sponsored research or on topics related to this research.

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

n/a

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.

UMB filed a patent in the field of imaging guided EP. An ongoing collaboration in the form of a research agreement with Biosense exists to further develop this technique.

The advisory board meeting for which this consulting agreement is written will further contact with other thought leaders and leading institutions in the country. Furthermore, my expertise in this area

will provide pertinent knowledge to Biosense in the development of this technique. It may also stimulate further research and grant money for 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.

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) **Assessment of utility of PET, MRI, CT to guide complex electrophysiological ablations. PI Timm Dickfeld, LuAnne Seipp is administrator, about 30k**
- 2) **Assessment of Safety of cooled-tip catheter for VT ablations, PI Timm Dickfeld, LuAnne Seipp is administrator, reimbursement is per patient**

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.

None

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.

N/a

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.

N/a

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.)

None

B. Ownership.n/a

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?)

N/a

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?

N/a

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?

N/a

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: **Consultant**

Responsibilities: **Discussion of current standard of care for VT ablations. Discussion of value of novel technologies and strategies to improve VT ablations.**

B. How much time per biweekly period 1 meeting, month _____, year _____ will you be providing to the entity? **With the possibility of future meetings during the term of the agreement, which expires on December 31, 2008.**

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

\$2500

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) N If no, please explain. ^{err TD}
The advisory board meeting is on Sunday, 10-26-07. I will not be on service that day. _{EP}

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) 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?

13.25%

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.

N/a

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.

N/a

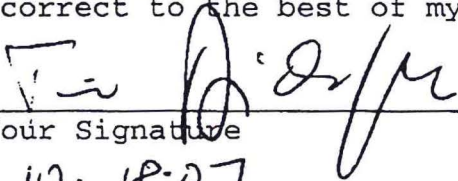
B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption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

N/a

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

10-18-07
Date

B. Supervisor's Statement

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

10/19/07
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: _____


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: _____

10/25/07
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.

11/29/07
Date

Bruce E. Kameel
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.

11/29/07
Date

[Signature]
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.

STEPHEN R. SHOROFKY, M.D., PH.D.,
Director
ERIC J. RASHBA, M.D.
R.E. HOOD, M.D.



ROBERT W. PETERS, M.D.
TIMM L. DICKFELD, M.D., PH.D.

UNIVERSITY OF MARYLAND PHYSICIANS, P.A.

Re: Conflict of Interest Disclosure for Biosense Webster

To the best of my knowledge, the disclosed documentation I am submitting accurately reflects all pertinent information. I have reviewed my research and financial interests with my Department Chair and we have discussed the resulting conflict of interest. I will take all necessary measures to minimize any actual or perceived clinical or scientific bias which may result from that conflict 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.



Timm Dickfeld
Assistant Professor of Medicine
Division of Cardiology/Department of Medicine

11/2/07

Date



UNIVERSITY OF MARYLAND

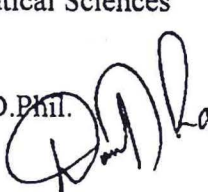
Office of the President

DAVID J. RAMSAY, DM, DPhil
President

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

MEMORANDUM

TO: Stephen W. Hoag, Ph.D.
Associate Professor
Department of Pharmaceutical Sciences
School of Pharmacy

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

RE: Conflict of Interest Disclosure #12-07-003

DATE: December 20, 2007

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated November 9, 2007. Your request involves proposed relationships between you and InfraTrac, Inc. You propose holding equity in InfraTrac, Inc. which was distributed to you as a result of a technology license granted by the University of Maryland Baltimore (UMB) to InfraTrac, Inc. This proposed relationship presents a conflict of interest issue because you plan to participate as a University of Maryland Baltimore (UMB) investigator on research of interest to InfraTrac, Inc. I believe that your association with InfraTrac, Inc. will facilitate research and development. I have determined that your relationship with InfraTrac, Inc. would not be a harmful interest, as described in the University System of Maryland (USM) Board of Regents' Policy on Conflicts of Interest in Research and Development. This exemption permits your association with InfraTrac, Inc. as described in your exemption request. In the absence of this exemption, your association with InfraTrac, Inc. would conflict with the Maryland Public Ethics Law, as well as USM and UMB policy.

The conditions of this exemption follow:

- Your business and financial relationship with InfraTrac, Inc. must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and subjects) participating in your research which is of interest to InfraTrac, Inc. Your relationship with InfraTrac, Inc. 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 InfraTrac, Inc. 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 UMB and InfraTrac, Inc. or except as necessary to the development of collaborative research proposals involving UMB and InfraTrac, Inc.
- All of the research you propose, all of the findings that result from or affect your InfraTrac, Inc. activities, and the conflict of interest issues surrounding your InfraTrac, Inc. 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 InfraTrac, Inc.
- If graduate students or postdoctoral fellows conduct research of interest to InfraTrac, Inc. 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 InfraTrac, Inc. 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.
- 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 and School review and approval of related documentation (such as UMB Grant Routing Forms and Time and Effort Reports). InfraTrac, Inc. must pay full compensation for the time of personnel and for other research costs as appropriate, and must pay full facilities and administrative costs unless waivers or reductions have been approved in accordance with UMB policy.
- It is understood that the estimated current value of InfraTrac, Inc. stock is \$1,000.00 per share, that you own 26 shares which represents 1.65% of the total equity in InfraTrac, Inc. As a condition of this exemption, you must hold the stock until the earliest of the following trigger events:
 - upon arms-length acquisition of all the stock or assets of InfraTrac, Inc. in return for cash; or
 - two years from the first commercial sale of a product embodying any of the licensed inventions developed in your research laboratory; or

- upon approval by the President of a written request for permission to sell the stock

These precautions are intended to mitigate criticism that inappropriate financial motivation may cause bias in your research. You will retain ownership of the stock at all times.

- You must 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 UMB Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

This exemption permits your association with InfraTrac, Inc. 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 InfraTrac, Inc., as disclosed in your exemption request, must be promptly disclosed to UMB (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: Dr. A Coop
 Dean N. Eddington
 Mr. J. Giffels
 Mr. J. Hughes
 Dr. M. Orlin

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 W. Hoag

University Title: Associate Professor

Division/Department or Administrative Unit: School of Pharmacy, Department of Pharmaceutical Sciences

FTE: yes Annual Salary: \$97,000

University Business Address: University of Maryland School of Pharmacy, 20 N Pine Street, PH room 620, Baltimore, MD 21201

Phone Number: 410-706-6865

Facsimile: 410-706-0346

E-mail Address: shoag@rx.umaryland.edu

B. About Your Immediate Supervisor

Name: Andy Coop

University Title: Associate Professor and Chair

University Business Address: _____

University of Maryland School of Pharmacy, 20 Penn Street,
HSF2 room 543, Baltimore, MD 21201

Phone Number: 410-706-2029

Facsimile: 410-706-5017

E-mail Address: acoop@rx.umaryland.edu

C. About the Entity

Name: InfraTrac

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

State in which it is organized: Delaware

General nature of its business activities: Start-up company
that has licensed UMB anti-counterfeit pharmaceutical technology
"Product Authentication"

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. None

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:

Sharon Flank, CEO

Give the person's business address: 800 W. Baltimore St. Ste.
105, Baltimore, MD 21201

Telephone Number: 202-251-4648

Facsimile Number: 202-363-3588

E-Mail Address: sflank@infratrac.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.

UMB (and hence inventors Drs. Hoag and Polli) have equity interest in InfraTrac, per license for "Product Authentication". Drs. Hoag and Polli are investigators on research (see MIPS application described in Section Four A) related to the technology of interest to InfraTrac. A potential conflict exists because of their financial interests in the outcome of the research.

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.

- 1. Results of findings will be submitted to a peer-reviewed journal**
- 2. Studies largely entail the use of near infrared (NIR) spectroscopy. NIR measurements are quantitative and highly objective.**
- 3. A post-doctoral fellow will be conducting the proposed studies. In addition to maintaining a laboratory notebook, the post-doctoral fellow will provide NIR data every two weeks to the department chair or her designee (e.g. Vice Chair for Research) for later validation.**
- 4. Drs. Hoag and Polli will discuss ongoing research and conflict of interest situation with Department Chair quarterly.**

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

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)? No significant costs are anticipated

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.

This exemption is requested in light of a MIPS proposal ("InfraTrac Anti-Counterfeiting", Oct 2007). This MIPS proposal seeks to facilitate the development of university-owned technology and intellectual property "Product Authentication".

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.

A MIPS proposal is being submitted for Oct 16:

InfraTrac Anti-Counterfeiting"

PI: Stephen Hoag

Total budget: \$100,000
Olcan Cetinkaya, X6-7598, School of Pharmacy
Barbara Pawloski, X6-3805, ORD

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.

UMB has licensed "Product Authentication" to Infratrac.

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.

Not applicable. Infratrac is the proposed MIPS partner

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.

none

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.)
stock

B. Ownership.

Individual x Joint

If joint, name of co-owner: _____

C. Value of your Ownership Interest. Current estimated dollar value \$26,000. Percent of total ownership 1.625% (26 shares of 1600 shares) _____.

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?)

UMB has distributed shares to Drs Hoag and Polli, per the Stock Issuance Agreement between InfraTrac and UMB. There is a one-year holding period and a requirement to grant right of first refusal to InfraTrac to purchase shares; there are no other conditions or encumbrances on the transfer of shares. However, I would abide by any conditions imposed by UMB as a means of managing my conflict of interest.

E. Will you purchase the ownership interest? (Y/N) N If so, what will you pay for it? per license
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?
Per license agreement

G. From what person or organization will you acquire your ownership interest?
From InfraTrac, via UMB

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: **not applicable**

Responsibilities: _____

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

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

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) _____ 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?

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.

Not applicable

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

Date

D. Statement of Chairperson

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

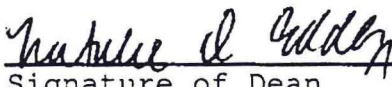
11/21/07
Date


Signature of Chairperson

E. Statement of Dean

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

11/9/07
Date


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
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: James E. Polli, Ph.D.
Professor
Department of Pharmaceutical Sciences
School of Pharmacy

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

RE: Conflict of Interest Disclosure #12-07-002

DATE: December 20, 2007

I approve, subject to compliance with the following conditions, your conflict of interest exemption request dated November 9, 2007. Your request involves proposed relationships between you and InfraTrac, Inc. You propose holding equity in InfraTrac, Inc. which was distributed to you as a result of a technology license granted by the University of Maryland Baltimore (UMB) to InfraTrac, Inc. This proposed relationship presents a conflict of interest issue because you plan to participate as a University of Maryland Baltimore (UMB) investigator on research of interest to InfraTrac, Inc. I believe that your association with InfraTrac, Inc. will facilitate research and development. I have determined that your relationship with InfraTrac, Inc. would not be a harmful interest, as described in the University System of Maryland (USM) Board of Regents' Policy on Conflicts of Interest in Research and Development. This exemption permits your association with InfraTrac, Inc. as described in your exemption request. In the absence of this exemption, your association with InfraTrac, Inc. would conflict with the Maryland Public Ethics Law, as well as USM and UMB policy.

The conditions of this exemption follow:

- Your business and financial relationship with InfraTrac, Inc. must be disclosed by you to anyone (including, but not limited to, collaborating faculty, staff, trainees and subjects) participating in your research which is of interest to InfraTrac, Inc. Your relationship with InfraTrac, Inc. 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 InfraTrac, Inc. 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 UMB and InfraTrac, Inc. or except as necessary to the development of collaborative research proposals involving UMB and InfraTrac, Inc.
- All of the research you propose, all of the findings that result from or affect your InfraTrac, Inc. activities, and the conflict of interest issues surrounding your InfraTrac, Inc. 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 InfraTrac, Inc.
- If graduate students or postdoctoral fellows conduct research of interest to InfraTrac, Inc. 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 InfraTrac, Inc. 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.
- 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 and School review and approval of related documentation (such as UMB Grant Routing Forms and Time and Effort Reports). InfraTrac, Inc. must pay full compensation for the time of personnel and for other research costs as appropriate, and must pay full facilities and administrative costs unless waivers or reductions have been approved in accordance with UMB policy.
- It is understood that the estimated current value of InfraTrac, Inc. stock is \$1,000.00 per share, that you own 26 shares which represents 1.65% of the total equity in InfraTrac, Inc. As a condition of this exemption, you must hold the stock until the earliest of the following trigger events:
 - upon arms-length acquisition of all the stock or assets of InfraTrac, Inc. in return for cash; or
 - two years from the first commercial sale of a product embodying any of the licensed inventions developed in your research laboratory; or

- o upon approval by the President of a written request for permission to sell the stock

These precautions are intended to mitigate criticism that inappropriate financial motivation may cause bias in your research. You will retain ownership of the stock at all times.

- You must 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 UMB Conflict of Interest Officer, Mr. Joe Giffels (x6-1853), or to my office.

This exemption permits your association with InfraTrac, Inc. 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 InfraTrac, Inc., as disclosed in your exemption request, must be promptly disclosed to UMB (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: Dr. A Coop
Dean N. Eddington
Mr. J. Giffels
Mr. J. Hughes
Dr. M. Orlin

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: _____ James E. Polli _____

University Title: _____ Professor _____

Division/Department or Administrative Unit: _____

_____ School of Pharmacy, Department of Pharmaceutical

Sciences _____

FTE: _____ yes _____

Annual Salary: _____ \$102,200 _____

University Business Address: _____ University of Maryland School of
Pharmacy, 20 Penn Street, HSF2 room 623, Baltimore, MD 21201

Phone Number: _____ 410-706-8292 _____

Facsimile: _____ 410-706-5017 _____

E-mail Address: _____ jpolli@rx.umaryland.edu _____

B. About Your Immediate Supervisor

Name: _____ Andy Coop _____

University Title: _____ Associate Professor and Chair _____

University Business Address: _____

__ University of Maryland School of Pharmacy, 20 Penn Street,
HSF2 room 543, Baltimore, MD 21201

Phone Number: __410-706-2029__

Facsimile: ____410-706-5017__

E-mail Address: _acoop@rx.umaryland.edu_____

C. About the Entity

Name: _____ InfraTrac_____

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

State in which it is organized: ____Delaware_____

General nature of its business activities: __Start-up company
that has licensed UMB anti-counterfeit pharmaceutical technology
'Product Authentication'

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. __None_____

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:
__Sharon Flank, CEO_____

Give the person's business address: __800 W. Baltimore St. Ste.
105, Baltimore, MD 21201_____

Telephone Number: __202-251-4648_____

Facsimile Number: __202-363-3588_____

E-Mail Address: ____sflank@infratrac.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.

UMB (and hence inventors Drs. Hoag and Polli) have equity interest in InfraTrac, per license for 'Product Authentication'. Drs. Hoag and Polli are investigators on research (see MIPS application described in Section Four A) related to the technology of interest to InfraTrac. A potential conflict exists because of their financial interests in the outcome of the research.

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.

1. Results of findings will be submitted to a peer-reviewed journal
2. Studies largely entail the use of near infrared (NIR) spectroscopy. NIR measurements are quantitative and highly objective.
3. A post-doctoral fellow will be conducting the proposed studies. In addition to maintaining a laboratory notebook, the post-doctoral fellow will provide NIR data every two weeks to the department chair or her designee (e.g. Vice Chair for Research) for later validation.
4. Drs. Hoag and Polli will discuss ongoing research and conflict of interest situation with Department Chair quarterly.

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

Is the entity prepared to pay the costs associated with implementing these suggestions (y/n)? No significant costs are anticipated

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.

This exemption is requested in light of a MIPS proposal (''InfraTrac Anti-Counterfeiting'', Oct 2007). This MIPS proposal seeks to facilitate the development of university-owned technology and intellectual property ''Product Authentication''.

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.

A MIPS proposal is being submitted for Oct 16:
InfraTrac Anti-Counterfeiting'
PI: Stephen Hoag

Total budget: \$100,000

Olcan Cetinkaya, X6-7598, School of Pharmacy

Barbara Pawloski, X6-3805, ORD

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.

UMB has licensed 'Product Authentication' to Infratrac.

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.

Not applicable. Infratrac is the proposed MIPS partner

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.

none

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.)
stock

B. Ownership.

Individual _____

Joint _____

If joint, name of co-owner: _____

C. Value of your Ownership Interest. Current estimated dollar value ___\$26,000_____. Percent of total ownership ___1.625% (26 shares of 1600 shares)_____.

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?)

UMB has distributed shares to Drs Hoag and Polli, per the Stock Issuance Agreement between InfraTrac and UMB. There is a one-year holding period and a requirement to grant right of first refusal to InfraTrac to purchase shares; there are no other conditions or encumbrances on the transfer of shares. However, I would abide by any conditions imposed by UMB as a means of managing my conflict of interest.

E. Will you purchase the ownership interest? (Y/N) ___N___ If so, what will you pay for it? _____per license_____ 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?
Per license agreement

G. From what person or organization will you acquire your ownership interest?
From InfraTrac, via UMB

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: not applicable

Responsibilities: _____

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

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

D. Will you use annual and other paid leave time for the work for the entity? (Y/N) _____ 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?

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.

Not applicable

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

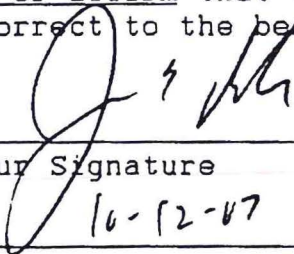
B. Relationship with other organizations. Describe any employment, ownership, or business relationship held by you or a spouse or dependent child in any business which could be affected (positively or negatively) by your relationship, or the results of your work, for the entity discussed in this exemption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

10-12-07

Date

D. Statement of Chairperson

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

10/24/07
Date


Signature of Chairperson

E. Statement of Dean

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

11/9/07
Date


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.