

<b>SOP: GRI 03</b> <b>Version No: 1</b> <b>Effective Date: 10/22/04</b>	<b>CONFLICT OF COMMITMENT AND INTEREST FOR RESEARCH PROFESSIONAL STAFF</b>	<b>Supersedes Document Dated:</b>
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## 1. SUMMARY

This policy presents and discusses circumstances that can create real or perceived conflicts of commitment and conflicts of interest for Staff. Establishes requirements for annual certifications and financial disclosures

## 2. GENERAL PRINCIPLES

### 2.1 Conflict of Commitment:

Research Institute Professional Staff members owe their primary professional allegiance to the Research Institute, and their primary commitment of time and intellectual energies should be to the education, research and scholarship programs of the institution. The specific responsibilities and professional activities that constitute an appropriate and primary commitment will differ across divisions and departments, but they should be based on a general understanding between the Staff member and his or her Center/Division Director and the Associate Vice President of Research.

Even with such understandings in place, however, attempts of Staff to balance Research Institute responsibilities with external activities--such as consulting, public service or pro bono work--can result in conflicts regarding allocation of time and energies. Conflicts of commitment usually involve issues of time allocation. Whenever an individual's outside consulting activities (as defined in the Research Institute's policy on outside consulting) exceed the permitted limits (normally thirteen days per quarter), or whenever a full-time Staff member's primary professional loyalty is not to the Research Institute, a conflict of commitment exists.

### 2.2 Conflict of Interest:

A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the Maine Medical Center or the Research Institute such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.

Conflicts of interest are common and practically unavoidable in a modern research institute. At the Research Institute, conflicts of interest can arise out of the fact that a mission of the Research Institute is to research new ways to provide care. This mission may involve the transfer of knowledge gained through Research Institute research and scholarship to the private sector. Two

important means of accomplishing this mission include Staff member consulting and the commercialization of technologies derived from research. It is appropriate that Staff be rewarded for their participation in these activities through consulting fees and sharing in royalties resulting from the commercialization of their work. It is wrong, however, for an individual's actions or decisions made in the course of his or her Research Institute activities to be determined by considerations of personal financial gain. Such behavior calls into question the professional objectivity and ethics of the individual, and it also reflects negatively on the Research Institute. The Research Institute is an institution of public trust; Staff must respect that status and conduct their affairs in ways that will not compromise the integrity of the Research Institute.

Staff members should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, the purposes of this policy are to educate Staff about situations that generate conflicts of interest, to provide means for Staff and Maine Medical Center and the Research Institute to manage conflicts of interest, to promote the best interests of students and others whose work depends on Staff direction, and to describe situations that are prohibited. Every Research Institute Staff member has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of commitment or interest arises, Staff are urged to discuss the situation with their Center/Division Director or the Associate Vice President of Research.

### **3. KEY PROVISIONS**

Below is a summary of the key provisions of this Policy. However, Staff are urged to read the document in its entirety to fully understand the spirit of these provisions, the bona fide exceptions, and requirements for compliance.

- 3.1 Staff must maintain a significant presence on campus (Scarborough or Portland) throughout each quarter they are on active duty.
- 3.2 Staff must not allow other professional activities to detract from their primary allegiance to Maine Medical Center or the Research Institute. For example, a Staff member on full-time active duty must not have significant outside managerial responsibilities nor act as a principal investigator on sponsored projects that could be conducted at the Research Institute but instead are submitted and managed through another institution.
- 3.3 Staff must foster an atmosphere of academic freedom by promoting the open and timely exchange of results of scholarly activities, ensuring that their advising of students, postdoctoral scholars, residents and interns is independent of personal commercial interests, and informing students and colleagues about outside obligations that might influence the free exchange of scholarly information between them and the Staff member.
- 3.4 Staff may not use Research Institute resources, including facilities, personnel, equipment, or confidential information, except in a purely incidental way, as part of their outside consulting activities or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the Research Institute.
- 3.5 Staff must disclose on a timely basis the creation or discovery of all potentially patentable inventions created or discovered in the course of their Research Institute activities or with more than incidental use of Research Institute resources. Ownership of such inventions

must be assigned to the Research Institute regardless of source of funding. The inventor will share in royalties earned.

- 3.6 Staff must disclose to the Maine Medical Center or the Research Institute whether they (or members of the immediate family, as defined below) have consulting arrangements, significant financial interests (also defined below), or employment in an outside entity before the Maine Medical Center will approve the following proposed arrangements between such entities and the Maine Medical Center: a) gifts; b) sponsored projects; c) technology licensing arrangements; and d) procurements. In such cases, formal Maine Medical Center approval will be required prior to entering into each proposed arrangement.
- 3.7 In situations in which the objectivity of a Staff member could reasonably be questioned, the Center/ Division Director shall inform the Office of Research Administration (ORA) such that the Oversight Committee can review the appropriateness of the proposed research to be conducted at Maine Medical Center or the Research Institute, oversee the conduct of the research, and ensure open and timely dissemination of the research results. Such oversight will be required for all clinical trials raising questions of conflict of interest.
- 3.8 On an annual basis all Staff members must certify to their Center/Division Director their compliance with the Maine Medical Center's policies related to conflict of interest and commitment. They must also disclose information about their (and their immediate family members', as described below) financial relationships with outside organizations that are sponsors or potential sponsors of their teaching, medical practice or research programs or are otherwise involved in commercial relationships with the Maine Medical Center that involve the Staff member. In addition, Staff must disclose to the Center/Division Director or Associate Vice President of Research on an *ad hoc* basis current or prospective situations which may raise questions of conflict of commitment or interest, as soon as such situations become known to the Staff member.
- 3.9 The AVP, Research shall review and approve exceptions to this policy and establish procedures to ensure timely review of their Staff's annual and *ad hoc* disclosures of potential or apparent conflicts. Such procedures shall involve representatives from the Maine Medical Center's Staff as part of the reviewing body. Center/Division Directors and the AVP, Research will file their own annual disclosures and certifications of compliance Audits and Compliance. MaineHealth.
- 3.10 An Oversight Committee composed of the Associate Vice President of Research, the Chairman of the Institutional Review Board, Chairman of the Medical Research Committee and a representative from Finance must also approve all special cases outlined in section 3.6 above, interpret policy provisions, respond to Staff wishing to appeal AVP, Research decisions, and report to the Institutional official annually on the status of this policy and its implementation.
- 3.11 Should a Staff member wish to appeal a decision made by above committee, he or she may present the appeal to the VP, Medical Affairs or President, who will consider the case.

## **4. DISCUSSION AND DETAIL**

### **4.1 Presence on Campus:**

Appointment as a Staff member of the Research Institute confers the privilege and obligation to pursue teaching, research, scholarship, and clinical care (whichever are appropriate to the position held). In addition, Center/Division Directors are expected to participate in Research Institute governance, in the formulation of academic and research policy, and in the determination of the intellectual directions and academic and clinical priorities of the Research Institute. Fulfillment of these obligations requires a primary commitment of expertise, time, and energy.

A full-time appointment conveys an obligation for a Staff member to have a significant presence on campus (Portland or Scarborough), to be accessible to students, postdoctorals, residents, interns and staff, and to be available to interact with Research Institute colleagues throughout every quarter during which he or she is on active duty, unless the Center/Division Director or the Associate Vice President of Research has granted specific prior approval for extended or frequent absences from campus. Since requirements for field research and other reasons for absence from campus differ across the Research Institute, divisions should define for their Staffs what qualifies as inappropriate, extended or frequent absences.

### **4.2 Limitations on Outside Professional Activities:**

The Research Institute encourages Staff to become involved in the transfer of knowledge from the Research Institute research laboratories and clinics into the commercial marketplace. It is an appropriate role for the Research Institute to facilitate the transfer of the knowledge gained through academic research to applications which can benefit the general population. Moreover, experience gained by Staff in the course of outside professional activities can enhance their teaching and research or scholarship within the Research Institute. But the process of technology transfer can create the potential for conflicts of commitment and/or interest, particularly when there is opportunity for personal gain on the part of the Staff. The intent of this provision of the policy is to minimize these conflicts and provide means of managing them when they arise.

An implicit assumption underlying the Research Institute's "Outside Consulting Activities by Members of the Research Staff" policy is that such outside professional activities are a privilege and not a right and must not detract from a Staff member's full-time obligation to his or her Research Institute duties. When any outside activity detracts from the conduct of Research Institute duties, a conflict of commitment will result. Even activities such as pro bono work, government service in the public interest, and any outside employment unrelated to the Staff member's Research Institute responsibilities (therefore not included as "consulting" in the policy on outside consulting), should be managed so they do not take precedence over a Staff member's primary commitment to the Research Institute.

Outside professional activities can also generate conflicts of interest regardless of the time involved. For example, direction of a program of research or scholarship at another institution

that could be conducted appropriately at the Research Institute as part of the Staff member's normal duties can deprive the Research Institute students and colleagues of the benefits of the Staff member's primary intellectual energies. Another example is submitting research proposals through channels other than the Research Institute to support work that could be performed at the Research Institute. First, the use of Research Institute resources in the course of that work is practically unavoidable. Second, it becomes difficult, if not impossible, for the Research Institute to review and reward the contributions of Research Institute Staff and students for work managed and/or conducted elsewhere. Third, the action can result in situations that place students and staff in conflicts of interest. For these reasons Research Institute Staff members on active duty normally are prohibited from serving as principal investigators on sponsored projects submitted and managed through other institutions. This stipulation is not intended to limit Staff from participating in multi-site training or research programs. Nor is it intended to apply to circumstances in which the Staff member's research requires access to facilities not available at the Research Institute.

Significant management roles (those that involve supervision of the work of others and/or day-to-day responsibility for operating decisions) in private business typically are demanding both in terms of time and energy. It is unlikely that such roles can be fulfilled by the manager working only 13 days per quarter, the maximum time permitted for full-time Staff to engage in outside consulting activities. Because full-time Staff are expected to devote their primary energies and professional interests to their Research Institute obligations, they may not accept significant managerial responsibilities as part of their outside consulting activities.

Whenever Staff members are involved in research as part of their outside consulting or business activities, they must establish clear boundaries that separate their Research Institute and outside obligations, so as to avoid questions about their appropriate use of resources and attributions of products of their work.

### **4.3 Free and Open Exchange of Research Results:**

The intelIpty of the Research Institute as a community of scholars requires the free and open exchange of ideas and the results of scholarly activities. Staff are obligated to maintain an atmosphere free from unwarranted external influences. Students and collaborators must be able to pursue topics of interest, have access to available information and facilities, and be able to communicate the results of their work to other scholars and the public. Therefore, Staff must ensure that:

- a) the activities of students and post doctoral scholars are free from the personal commercial interests of the Staff member; and
- b) the work of students, staff, post-doctoral scholars and collaborators is not exploited in the course of a Staff member's outside obligations. To this end, Staff members should be open about their involvement with and obligations to outside third parties who could benefit from the work or ideas of their students, staff, and colleagues. Similarly, students, associates, and staff should have access to information about the sources of funds that support their research.

#### **4.4 Appropriate Use of Research Institute Resources, including Facilities, Personnel, Equipment, and Information:**

Staff may not use Research Institute resources, including facilities, personnel, equipment, or confidential information, except in a purely incidental way as part of their outside consulting activities or for any other non-Research Institute purposes. Inappropriate use of Research Institute resources includes the following:

- a) Assigning the Staff member's students, staff or postdoctoral scholars Research Institute tasks for purposes of potential or real financial gain of the Staff member rather than the advancement of the scholarly field or the students' educational needs.
- b) Involvement of the Staff member's students or staff in his or her outside consulting or business activities without prior approval of the Division Director or the Associate Vice President of Research;
- c) Granting access to external entities to Research Institute resources or services for purposes outside the Research Institute's missions, or offering inappropriate favors to outside entities in an attempt to unduly influence them in their dealings with the Research Institute;
- d) using for personal gain, or granting unauthorized access to others, of confidential information acquired through conduct of Research Institute business or research activities. Confidential information includes, but is not limited to, medical, personnel, or security records of individuals; proprietary knowledge about corporate anticipated material requirements or price actions; and proprietary knowledge of possible new sites for government operations or information about forthcoming programs or selection of contractors or subcontractors in advance of official announcements.
- e) Providing preferential access to research results, materials or products generated from Research Institute teaching or research activities to an outside entity for personal financial gain. (This would not preclude appropriate licensing arrangements for inventions, or consulting on the basis of sponsored project results where there is significant additional work or expertise involved.)

#### **4.4 Disclosure and Ownership of Intellectual Property:**

The Research Institute wishes to encourage Staff members to be involved in technology transfer as part of their Research Institute duties without raising questions as to their motives. However, Staff ownership of inventions created in the course of their Research Institute activities or with more than incidental use of Research Institute resources creates conflicts of interest. First, most research and scholarly work conducted at Research Institute has been supported directly and indirectly by numerous sources with which the Research Institute has entered into contractual agreements. It is the responsibility of the Research Institute to honor the terms of those contracts regarding commercialization of results of the work they sponsored. For Staff members to decide ownership of intellectual property based on source of support when they stand to gain financially from such decisions constitutes a serious conflict of interest. Second, for Staff members to claim ownership of an invention resulting from their Research Institute activities calls into question

whether they are using Research Institute resources for personal financial gain. Third, the opportunity for a Staff member to assume ownership of an invention and then grant exclusive access to it to a sponsor or potential sponsor of his or her Research Institute research creates an incentive for inappropriate relationships. Staff are expected to exercise scientific objectivity in the conduct of research and guidance of students and associates. To the extent that the financial interests of a Staff member and a corporate sponsor become intermingled, the scientific objectivity of the Staff member can be called into question.

To manage and minimize conflict over intellectual property rights, all potentially patentable inventions created or discovered by Staff in the course of their Research Institute activities, or with use of Research Institute resources, must be disclosed to the Research Institute on a timely basis. Ownership of these inventions must be assigned to the Research Institute regardless of source of funding. Institutional management of the commercialization of technologies developed using Research Institute resources guarantees that contractual obligations to sponsors are fulfilled. Research Institute management of technology also reduces the potential for individual conflicts of interest, since the institutional managers of the assets do not have personal financial interests in the outcomes of licensing processes nor do they participate in making academic or future research decisions.

In this context, "invention" includes tangible research property. The term does not, however, include books, scholarly articles, musical and artistic works, and other forms of educational media, title to which remains with the creator. In accord with academic tradition, except to the extent required by the terms of funding agreements, Research Institute does not claim ownership to pedagogical, scholarly, or artistic works, regardless of their form of expression. Such works may represent the personal or scholarly beliefs of the author. The protection of academic freedom of the Staff requires that the Research Institute not attempt, nor have the right, to control the content or distribution of such works. An additional consideration is that the Research Institute does not wish to accept liability for a Staff member's works that are individual forms of expression.

Ownership of computer software requires special consideration. Some forms of software are patentable, and thus must be assigned to the Research Institute. Other forms of software are more like books in that they are digital expressions of scholarly, artistic, or educational works, in which case title rests with the creator. Rights to software that is not patentable rest with the individual Staff creator except in the following circumstances: the work is supported by a direct allocation of funds through the Research Institute for the pursuit of a specific project, is commissioned by the Research Institute, or is otherwise subject to contractual obligations. Title to software created jointly with students or other Staff shall be jointly owned by the creators. Title to software created jointly by Staff members will be jointly owned between the Staff creator and the Research Institute. Staff must be aware, however, that the creation, upgrade, or maintenance of commercializable software, when done as part of a Staff member's Research Institute activities, can lead to the same types of conflicts of commitment and interest as patentable inventions. It is the responsibility of the Staff member to avoid such conflicts. One way of doing so is to voluntarily assign copyright and licensing authority to the Research Institute.

This policy is not intended to go beyond any contractual obligations to restrict the creator of a technology from placing his or her creation in the public domain if he or she believes that would be in the best interest of technology transfer, unless such an action is restricted by contractual obligations. Also, this policy is not intended to slow or restrict the transfer of technology, so if the Research Institute does not proceed in a timely manner to patent a technology and/or license it, the ownership will be reassigned to the creator at his or her request if permitted by contractual obligations. In those cases where the sponsor requires the Research Institute to take title, the Research Institute may recommend to the sponsor that ownership be assigned to the inventor.

When the Research Institute is successful in the licensing of a technology created by a Staff member, he or she will share in the royalties earned under the terms of the applicable Research Institute policy.

#### **4.5 Staff Involvement in Outside Entities Which Have Relations with Research Institute:**

Gifts, procurements, sponsored projects, or technology licensing arrangements between Research Institute and outside entities in which the involved Staff member (or members of the immediate family, which includes the Staff member's spouse or dependent children as determined by the Internal Revenue Service, or a domestic partner) has

- a) significant financial interests, or any employment or consulting roles, raise particular questions of potential or apparent conflicts of interest which require special ad hoc disclosures, review and approval.

For this purpose "significant financial interests" means current or pending ownership interests in an entity amounting to at least one-half percent (0.5%) of the company's equity or at least \$50,000 in ownership interests (except when the ownership is managed by a third party such as a mutual fund). Additionally, Staff members seeking funding from an external sponsor must ensure compliance with that sponsor's disclosure requirements.

Prior to the Research Institute entering into any of the following arrangements, the involved Staff member must submit to the Division Director and the Associate Vice President of Research a complete written disclosure of his or her current or pending relationship with the outside entity, the relationship of the proposed Research Institute activity to the entity, and means by which the Staff member will ensure separation of his or her Research Institute role from the Staff member's (or family members, as described above) role or interests in the company:

- a) gifts to Research Institute of cash or property which will be under the control, or will directly support the teaching or research activities of a Staff member from an entity in which that Staff member (or members of the immediate family as described above) has an employment or consulting arrangement and/or significant financial interests (as defined above);
- b) sponsored project proposals in which any of the involved investigators (or members of their immediate families as described above) have employment or

- consulting arrangements and/or significant financial interests in the proposed sponsor, or with proposed subcontractors, vendors, or collaborators;
- c) Research Institute technology licensing arrangements with companies for which the Staff inventor (or members of the immediate family as described above) has employment or consulting arrangements and/or significant financial interests; and
  - d) procurement of materials or services from an outside entity in which the Staff member (or members of the immediate family as described above) has employment or consulting arrangements and/or significant financial interests.

Common sense must prevail in the interpretation of these provisions. That is, if a reasonable person would question the relationship, it should be disclosed and approval sought for the proposed arrangement.

If such proposed arrangements are approved by the Associate Vice President of Research, the Staff member's disclosure and Associate Vice President of Research's findings and recommendations shall be submitted to the Institutional Official for final approval. The Associate Vice President of Research may convene an ad hoc committee to advise him or her on any such proposed arrangements. The committees may include other members of the Staff and/or individuals not otherwise affiliated with Maine Medical Center or the Research Institute, as long as none of them has vested interests in the outcome of the proposed arrangements.

#### **4.6 Situations Raising Questions of Scientific Objectivity:**

In cases where the Research Institute has approved arrangements as described in Section 6 above, or in the Clinical Trials Center (clinical trials) in which the investigators have personal financial interests, the scientific objectivity of the Staff member's activities may be questioned by reasonable people. To address these situations, the AVP, Research may forward the matter to the Oversight Committee for review of the appropriateness of the proposed activity, to monitor the conduct of the activity (including use of students and postdoctoral scholars), and to ensure open and timely dissemination of the research results.

Clinical trials involve particularly sensitive issues in those cases where the investigator has personal financial interests in the outcomes. The demand for therapeutics requires that new agents be developed and tested. The processes that must be followed in the testing and development of therapeutics raise an inherently contradictory situation for Staff, since frequently the inventors of therapies or medical devices are those who do research on the disease in question, are the leaders in the field, and are the most qualified to carry out pre-clinical and clinical testing. Also, the most qualified laboratories and individuals to conduct trials may receive, or be candidates to receive, research support from the external organization. In neither case could the Staff member be disinterested with respect to the outcome of the trials.

Therefore, the Staff member must take appropriate steps to guarantee objective evaluation of the agent or device, especially for any clinical trials (FDA phase I, II and phase III). Testing might involve other members of the Center/Division, but if the Staff member is a Center/Division Director, the referral for testing the therapy/device to another Staff member (particularly to a junior Staff member) may carry implied coercion. InteIPty should be protected by an

independent oversight group for evaluation and monitoring of the research (e.g., to an ad hoc committee appointment by the Associate Vice President of Research) whenever:

- a) a Staff member is involved in clinical trials of his or her inventions;
- b) a company licensed to use a Staff member's invention is sponsoring the trial;
- c) there may exist a reason to question a Staff member's objectivity;
- d) the outcome of the trial could be seen as influencing existing or potential research support, or
- e) such testing is referred to other members of the Staff member's division or department.

#### **4.7 Certification of Compliance:**

On an annual basis all Staff members must certify to the AVP, Research their compliance with Research Institute's policies related to conflict of interest and commitment, and disclose their prior academic year's consulting activities for and/or significant financial interests in outside organizations that support their Research Institute teaching or research program. Staff members must also disclose other arrangements with outside organizations with which they are involved as described above in Section 6. In addition, Staff must disclose if they have served as principal investigators or managers of outside research or business activities in their professional fields, or if they have involved their students or staff in their outside consulting or business activities. When conditions described in Section 6 pertain, Staff members must also provide similar information about employment, outside consulting activities and/or financial interests of members of the immediate family (as described above). Staff members supply this information for confidential review by the AVP, Research.

Staff members must disclose to the AVP, Research on an ad hoc basis current or prospective situations which may raise questions of conflict of commitment or interest, as soon as such situations become known to the Staff member.

#### **4.8 Responsibilities of Center/Division Directors:**

Each Center/Division Director is responsible for the timely collection and review of annual certifications as well as ad hoc disclosure reports. The Center/Division Director should use his or her discretion and knowledge of local conditions to set up a system that works well for the Center/Division Director. Each Center/Division Director's plans for distribution, receipt, processing, and review of disclosure forms shall be submitted to and approved by the Associate Vice President of Research. However, if for reasons of confidentiality, a Staff member wishes to have his or her disclosure reviewed personally and exclusively by the Associate Vice President of Research. The Associate Vice President of Research is responsible for reviewing and granting exceptions for many of the provisions of this policy, but he or she must report all such exceptions to the Oversight Committee.

The Associate Vice President of Research will file their own annual disclosures and certifications of compliance with the Institutional Official.

#### **4.9 Responsibilities of the Associate Vice President of Research:**

The Associate Vice President of Research is the Research Institute officer responsible for interpreting and overseeing implementation of and compliance with this Policy. He or she is responsible for reviewing and approving each Center/Division Director's mechanisms for implementing this Policy and shall report annually to the Oversight Committee on the effectiveness of the Policy throughout the Research Institute. In addition, the Associate Vice President of Research shall adjudicate situations in which Staff wish to appeal a decision of a Center/Division Director. The Associate Vice President of Research shall approve arrangements for situations discussed in Section 6, or may delegate this authority to the Oversight Committee. In any case, however, the Associate Vice President of Research is expected to ensure that this policy is implemented with reasonable consistency across the Research Institute. To this end he or she will monitor exceptions to this policy granted by Center/Division Directors.

#### **4.10 Appeals of decisions made by the Associate Vice President of Research:**

Should a Staff member wish to appeal a decision made by the Associate Vice President of Research or the Oversight Committee, he or she may present the appeal to the Institutional Official, who will consider the case.

#### **5.0 RELATED RESEARCH POLICY(S)**

- GRI 01 Principles Concerning Research
- IP 04 Outside Consulting Activities by Members of the Staff
- GRI 04 Conflict of Commitment and Interest for Staff
- IP 02 Maine Medical Center Investments in Start-Up Companies Involving Research Institute Staff
- IP 03 Equity Acquisition in Technology Licensing Agreements
- IP 01 Inventions, Patents and Licensing

#### **6.0 AUTHORITY**

The Associate Vice President for Research is responsible for interpretation and overall coordination of this Policy.