

## **Society of General Internal Medicine**

### **POLICY ON ACCEPTANCE AND DISCLOSURE OF EXTERNAL FUNDS**

Originally approved by Council, December 2005

Amended November 2018

#### **INTRODUCTION**

The primary goal of the Society of General Internal Medicine is to support its members in their efforts to promote improved patient care, teaching, and research in primary care and general internal medicine. The SGIM Council may promote these goals by accepting external funds such as grants, sponsorships, or gifts in support of activities designed to meet this goal. This policy provides guidelines for the negotiation and acceptance of such funds, as well as regular disclosure to the membership of the sources and amounts of external funding accepted by SGIM. It provides guidance for all external funding relationships and is not limited to commercial relationships. External funds targeted for support of national and regional SGIM meetings are also covered by this policy. Final decisions on the interpretation of this policy as it is applied in practice are the responsibility of the SGIM Council. Individuals and groups who solicit funds on behalf of SGIM should be familiar with these guidelines.

#### **BACKGROUND**

External funds may help SGIM pursue its mission in several ways. Examples include:

- Helping SGIM undertake initiatives to promote patient care, teaching, and research in general internal medicine, especially in reorganizing medicine to better integrate generalism into medical practice;
- Improving the quality of SGIM meetings by allowing the Society to reimburse speakers, provide honoraria, furnish amenities, give scholarships and awards, or offer general programming that might otherwise be unavailable; and
- Helping SGIM provide services of value to members that advance the goals of the society, such as the SGIM website, email, and listserver systems.

In short, external funds potentially allow SGIM to pursue worthwhile activities that it might otherwise have to forgo.

Financial relationships with external funders may create potential ethical conflicts for SGIM, as they would for any other not-for-profit institution organized to pursue a worthy mission and to promote a noble set of values. Financial relationships with external funders can raise ethical questions about whether these relationships might result in decision-making that deviates from the organization's mission and values. Such

deviations may be very subtle. Two common sources of such biased decision-making are situations of dependency and conflicts of interest. Excessive dependency on external sources of funding may influence an organization to make decisions that deviate from its mission and values in order to obtain or sustain financial support. The search for support may lead to deviation in favor of the interests of the funder, or it may become a substantial activity in its own right that detracts from the organization's focus on its core mission and values. Conflicts of interest are another source of potential concern. Conflicts of obligation are common, but a conflict of obligation becomes an actual conflict of interest when the funding source actually influences or gives the appearance of influencing an organization to make decisions that deviate from its mission and values in favor those of the funder. Conflicts of interest can arise either for individual members who exercise decision-making authority within an organization or for the organization as a whole. Concerns about dependency and conflict of interest are particularly acute in two situations: when external funding is from organizations with interests that differ substantially from those of the recipient (either for-profit or not-for-profit entities); and when the amount of external funding, particularly from a single source, is of such magnitude that it will be difficult to carry out a valued activity in the absence of external funding. The more valued the activity is, and the greater the understanding that continuing that activity in perpetuity is important to the organization (which is especially the case when that activity expresses its core values), the greater the concern.

With these observations of the benefits and risks of external funding in mind, SGIM has established the following guidelines for the acceptance of external funds.

## **GUIDELINES FOR THE ACCEPTANCE OF EXTERNAL FUNDS**

### **Definition of Terms.**

For the purposes of this policy, the following terms will be used:

- **Non-health care-related entities** produce or sell goods or services that neither underwrite nor purport to provide direct health benefits to patients (for example, entities that make automobiles, or sell financial advice).
- **Health care-related entities** can be subdivided into
  - those groups that make or sell goods or services that purport to provide direct health benefits to patients (for example, pharmaceutical, device, and diagnostics companies, insurance companies; hospitals)
  - those groups that provide services or benefits to health care providers (e.g., professional staffing companies, or entities that sell medical education to clinicians or sell information technology to health care providers)

Note: Either type of entity may be a for-profit or non-profit.

## **Projects in General.**

SGIM should accept external funds only for high quality projects that are:

- consistent with the SGIM mission, “To be the professional home for innovators and scholars in academic general internal medicine leading the way to better health for everyone”;
- judged to be particularly well suited to be carried out by SGIM as an organization (especially in contradistinction to individual Society members or groups of members working through their own institutions), especially if SGIM is to be the primary recipient of external funds for the proposed project.

The authors of this policy acknowledge that there will be subjectivity in decisions regarding which projects are particularly well suited to be carried out by SGIM (particularly as primary recipient of external funding). In general, projects for which SGIM is particularly well suited create the opportunity for participation of large numbers of SGIM members in ways that would be difficult or impossible to arrange through standard mechanisms of funding to hospitals and universities. When more than one SGIM member independently approaches the organization regarding obtaining funding for a project of a similar nature, and particularly when SGIM’s participation would be mutually exclusive, every effort should be made to foster collaboration among the interested individuals so that a single project proposal results. If, despite these efforts, more than one proposal is submitted for a similar project, and SGIM’s participation is mutually exclusive, these projects would be reviewed in parallel.

## **Restrictions on Accepting Funds.**

- A. SGIM should not accept external funds, either directly or indirectly as a subcontractor to another entity, from for-profit companies (or not-for-profit entities funded largely by for-profit companies) for research or educational projects (including *individual* precourses, workshops or other presentations at the SGIM national or regional meetings) related to specific diseases, or to pharmaceuticals, medical devices, diagnostics, or other products or services purported to have direct health benefits or direct costs to patients (regardless of whether the products are sold by that particular external funder). Such funding is problematic, as the intent would appear to be primarily promotional; that is, to directly or indirectly (through greater recognition of the disease in the population) encourage wider use of medical products, to the benefit of the sponsor. These potential benefits and thus the sponsor’s intent might not always be readily apparent, due to relationships among companies and new products that might be in their pipelines.

However, general meeting support (as opposed to support for specific sessions) for the annual or regional SGIM meetings can be solicited from for-profit companies once the content of the meeting has been defined and is permissible even if some of the meeting content may relate to specific diseases or treatments of interest to the company providing the general meeting support. This also applies to potential exhibits, which have a separate review process to determine eligibility (see below).

- B. SGIM will not accept external funding from companies that deal in products and services that are believed to be detrimental to the public good. For example, SGIM shall not accept external funds from companies that make or sell products that unequivocally are injurious to health or the environment, such as companies that make or sell tobacco products, including other companies owned by tobacco companies, or their parent companies. Final judgments about whether products or services are detrimental to the public good will be the responsibility of the SGIM Council.
  
- C. Finally, dependence is potentially created when SGIM's core operations become too reliant on external funding. External funds that "pass through" SGIM to other individuals and groups for the accomplishment of specific projects or for awards do not create dependence, nor do funds that are saved by SGIM for future disbursement for these purposes. An exception would be external funds for payment of travel expenses for SGIM members to speak at regional or national meetings, or trainee travel awards, which do have the potential of creating dependence. The SGIM operating budget best reflects expenses for core activities; it is the proportion of external funds that comprise the operating budget that, if too high, raise concerns about dependence. In this context, "internal" funds are considered revenues from dues, meeting and course registrations, serial publications (including subscriptions and royalties from the Journal of General Internal Medicine), sales of products and services to members, and member donations. "External" funds are revenues from all other sources. External funds used specifically for the Society's operations and included in the annual operating budget should not comprise more than 33% of the Society's annual operating budget. In addition, the following limits apply to external funds from various sources: no more than 15% of the operating budget from any single not-for-profit entity; no more than 15% of the operating budget from any non-health care-related for-profit entity; and no more than 5% of the operating budget from any health care-related entity, as well as no more than 10% of the operating budget from all health-care related entities combined (see Appendix 1 for details of these calculations).

These limits will also apply to the operating budgets of each SGIM region (which generally will be dominated by the costs of the respective regional meetings), with the

exception that the limit on funding from any single for-profit source will be \$2500 or 5% of the operating budget, whichever is higher.

As the percentage of the operating budget provided by any external funder or class of funders cannot be calculated until the end of a fiscal year, percentages may unintentionally exceed the specified limits by small amounts on occasion. In these circumstances, any excess funds accepted beyond the limits in this policy must be transferred to one of SGIM's endowment accounts.

To allow SGIM to conduct more ambitious projects, external funds for a specific project from not-for-profit entities and non-health care related for profit entities may also be placed in a restricted account for use only for project-specific expenses (overhead on the project funds would enter the operating budget as usual). Once placed in such an account, any funds cannot be brought back into the SGIM operating budget or be used for other purposes. If any funds are left in the account once the project is completed, and the external funder approves, those funds can only be transferred into another SGIM restricted account for a specific purpose. External funds that are placed in such a restricted fund and are used for project-specific and not core expenses reduce the risk of dependence and therefore do not count toward this policy's funding limits.

### **Overview of Project Factors**

Educational Projects. SGIM must retain ultimate control over educational content, selection of speakers, review of educational materials, selection of research for presentation, or other public activities with scientific content that are financed with external funds. Precourses, workshops, or other educational presentations at the national and regional meeting are considered educational projects from the perspective of this policy. When external funding is solicited for national or regional meetings, the meeting program should be determined before funding is solicited, to ensure the independence of meeting program planning from the interests of external funders.

Research Projects. SGIM will retain control of the selection of project personnel and other activities for the conduct of research activities for which the Society accepts external funding.

Use of Human Subjects. If an externally funded research or educational project involving SGIM requires use of human subjects in any way, it is the responsibility of the project's proponents to obtain appropriate IRB approval(s) from their own institution(s). SGIM will not maintain a central IRB.

Freedom to Publish Results. The proponents of any externally funded research or educational project involving SGIM shall have the right to publish their findings without interference from the external funder. Only nonbinding, expeditious review and comment on written results by the external funder is acceptable. The Society

encourages but neither requires nor commits to publication of the results of these projects in the *Journal of General Internal Medicine*.

Intellectual Property. When SGIM serves as the primary entity accepting external funds for a research or educational project, SGIM reserves the right to all intellectual properties resulting from the project. When SGIM collaborates with another entity that is the primary recipient of funds for the project, that entity, usually the project proponent's academic institution, will generally have the right to all intellectual properties resulting from the project. In the latter case, an agreement regarding intellectual property must be documented in writing between the concerned institutions and SGIM and approved by Council.

Budgets. When externally funded research or educational projects require using SGIM resources at the national office, a budget for those activities should be negotiated between the CEO and the SGIM members responsible for the project to cover the direct costs of SGIM's participation. In general, to cover SGIM's indirect costs, an additional percentage reflecting the Society's overhead costs as negotiated with the Federal government will be added to the budgeted direct costs (but not to other funds that "pass through" SGIM to other parties for completion of the project). The final budget for each project, including any deviations from the usual overhead rate, must be approved by the SGIM Treasurer. External funds for awards, which reflect acknowledgment for completed work or funding for new work or activities to be done independently of SGIM, and which require minimal use of resources at the SGIM central office, as judged by the CEO, do not require a specific budget. Rather, a reduced overhead rate of at a minimum 10% will be added to the total amount of the award to account for the Society's costs for publicizing, selecting, and administrating the award. External Funds solicited for such awards will be kept in restricted accounts that cannot be used for other purposes (especially operations). Only when funds are disbursed for an award will the Society's overhead be applied to the disbursed amount, and the amount of the overhead be included in the numerator of the calculation of the proportion of the operating budget derived from external funding in that year.

Projects with an Internal Selection Process. When SGIM accepts external funds for research or educational projects that involve a competitive selection process with submitted proposals, the external funder can have limited input in the selection criteria for which proposals will receive funding and will receive information about which proposals did and did not receive funding. However, final funding decisions will be made by a group designated by SGIM, independent from the external funder. This group may include both SGIM and non-SGIM members.

Awards. When SGIM accepts external funds for awards, which reflect acknowledgment for work already completed, awardees will be selected based on criteria established by SGIM. The sponsor may have limited input in the selection criteria but SGIM retains

ultimate control over selection of the award recipient. The sponsor can impose no obligations on the recipient of an award.

Advertising. The *Journal of General Internal Medicine* may accept advertisements for medically-related products and services. Final judgment regarding the appropriateness and acceptability of advertisements rests with the Journal's editorial staff. Advertising (except for classified advertising of positions available and announcements) will not be accepted for the Society's other publications, including the *SGIM Forum* and web site.

Exhibits and Exhibitors: SGIM may contract with vendors (exhibitors) to provide an exhibit (table, booth, or equivalent) about their products or services at SGIM's annual and regional meetings. The same policies that apply to external funding in this document apply also to exhibits and exhibitors. Final decisions are at the discretion of the SGIM Council. The procedure for reviewing such vendors is as follows.

- Allowable exhibitors/exhibits are at the discretion of the SGIM Chief Executive Officer and include non-health care related entities or institutional fellowship programs, institutional recruitment offices, recruiting firms, non-profit and governmental educational programs (e.g., preventive health education), and publishing companies.

SGIM will use a review process by selected Finance and Ethics committee representatives to assess and determine acceptable exhibits in the following categories.

- Potential exhibits/exhibitors undergo expedited review by the chairs or designated member of the Finance and Ethics Committees. These are proposals from companies that do not meet criteria for an allowable exhibitor/exhibit, and do not sell products or services purported to have direct health benefits or direct costs to patients. This category may include health care related entities that sell products or services to health care providers that do not have direct health benefits to patients (i.e., that only have indirect benefits to patients, such as medical education or information technology).
- Other exhibits/exhibitors are usually not allowable and may only be considered after review by the full Ethics and Finance Committees. These include organizations that provide products or services purported to have direct health benefits or direct costs to patients, and organizations that sell drugs or devices for use by patients.

Access to SGIM Members. Access to SGIM members or to recipients of external funds shall not be a condition of support from an external funder (including exhibitors) including access through talks by representatives of the external funder at regional or national meetings.

Disclosure. SGIM should disclose all sponsored activities that are partially or completely financed by external funds, including but not limited to research grants, presentations

and publications, and support of policy efforts (see subsequent section of procedures for disclosure).

Business Relationships. SGIM may establish a business relationship with an individual, group, or organization to endorse, develop, distribute, or sell products or services; for example, journals, books, software, or other educational products. However, acceptance of any funds that come to SGIM from these relationships will be governed by these guidelines for external funding of projects. For example, SGIM shall not receive funding to endorse, develop, distribute, or sell products such as pharmaceuticals, medical devices, diagnostics, or other products purported to have a direct health benefit to patients. In addition, SGIM shall not enter business relationships with companies that make or sell tobacco products, including other companies owned by tobacco companies, or their parent companies.

Acknowledgments. Tasteful acknowledgment of external funders may be made in the Society's publications, meeting materials, or reports of project results, as appropriate. These acknowledgments should not advertise any products or services of the funder. Ultimate decisions about the tastefulness and appropriateness of any acknowledgments of external funding rests with the SGIM Council.

Because the opportunities for external funding for valuable projects are varied and to some extent unpredictable, exceptions to these guidelines may be appropriate in some circumstances. Any exceptions, however, must be approved by the SGIM Council. As circumstances may also change over time, this policy should be reviewed at least every three years by Council and amended if necessary. The SGIM Council will make the final determination of any funding that is not resolved elsewhere in this policy or if there remains any dispute.

## **PROCEDURES FOR REVIEWING EXTERNAL FUNDING**

- All SGIM members, staff, or consultants involved in negotiations with external funders should be familiar with this policy. The initiation of the approval process should begin early in any quest for external funding, ideally when an SGIM member or group of members first conceives of a project requiring SGIM's participation and external funding, or when an SGIM member or group of members is first approached by an external funder about a potential project requiring SGIM's participation.
- General contributions, including contributions for the national meeting and for awards, will be handled directly by the Finance Committee. All general contributions, except unrestricted educational grants less than \$5,000, will also be reviewed by the chair of the Ethics Committee. Most general contributions under \$5,000 will not raise concerns from the perspective of this policy. However, any general contribution that raises concerns will undergo a full Ethics Committee review (see below). For unrestricted educational grants less than \$2,500 for regional meetings, the regional officers can accept contributions that fall within this policy, in

place of the Finance Committee. Regional officers should feel free to consult the Finance and/or Ethics Committee Chairs if they have questions about particular contributions and must do so for contributions larger than \$2,500.

- Proposals for research or educational projects requiring external funding and for which the applicant(s) request SGIM's involvement should come from an SGIM member or groups of members (with one member designated as the main point of contact).
- At minimum, proposals for research or educational projects should include a standard cover page and a three-page (maximum) abstract describing the project's objectives, methodology, timetable, the estimated budget and proposed source of external funding, human subjects/IRB issues, and how it satisfies the SGIM guidelines for the acceptance of external funds. A biographical sketch of each key participant should be included. Additional supporting materials may be included. A template for proposals for externally funded research or educational projects is included as Appendix 2 of this policy.
- Proposals for research or educational projects should be submitted to the SGIM Finance Director, who will triage them as follows:
  - Research projects will go to the Chair of the Research Committee
  - Educational projects will go to the Chair of the Education Committee
- Exhibits will be reviewed as per the tiered system using application form and designated reviewers (CEO for first tier, Ethics/Finance chairs for second tier).

The Chairs of these committees will preliminarily review the proposal (in consultation with the SGIM Chief Executive Officer), focusing on compliance with the external funding guidelines and feasibility of the project, and either reject the proposal, return the proposal to the applicant(s) for revision, or forward the proposal along for a full review. Full review would be undertaken by a subcommittee of each committee consisting of three members, with approval to move the project forward required from at least two of the three members. Reviewers would be asked to declare any potential conflicts of interest in their evaluation of assigned proposals; occasionally, such a declaration may lead the Committee Chair to replace a reviewer.

- In parallel, each proposal for external funding for research or educational projects forwarded for a full review by the Research or Education Committee will also be reviewed in parallel by the Chair of the Ethics Committee. If any concerns are raised, the Chair of the Ethics Committee will appoint three Ethics Committee members to perform a full Ethics review. Once again, approval to move the project forward would be required by at least two out of the three members.
- During the period of full review, the Ethics Committee may ask the Council to post the proposal on the SGIM web site, and all SGIM members with active email addresses in the Society's membership database would receive a brief message about the nature of the project under review, referring them to the full proposal. Any concerns of individual members, especially regarding competition with their own efforts, should be communicated to the Chair of the Research or Education

Committee within two weeks of the posting. These messages would in turn be forwarded to the Committee members performing the full review and considered in the deliberations regarding project approval. The Council reserves the right to decide whether posting of the proposal is important enough to justify the time and effort needed to obtain input from the membership.

- Projects approved to move forward by both the Education or Research Committee and the Ethics Committee would then be reviewed by the SGIM Treasurer, particularly regarding whether the new funding would bring the total amount of external funding above acceptable thresholds for the year and forwarded to the SGIM Council for final approval at a monthly conference call or meeting. The goal of the entire review process should be to accept or reject proposals within 60 days of submission.
- SGIM acknowledges that occasionally opportunities for externally funded research or educational projects may be time-limited. If a decision on SGIM's participation must be made in less than 60 days, a letter requesting an expedited review can accompany the proposal. Decisions regarding the desirability, practicality, and mechanisms of an expedited review will be made by the CEO, in consultation with the Chairs of the appropriate Committees (Research or Education and Ethics).
- If a proposal is not recommended for further consideration at any stage of the process, the proponents may appeal the decision in writing to the SGIM Executive Committee. The Executive Committee may confirm or over-ride the original decision; in the latter case, the proposal would proceed to (but not circumvent) the next step in the review process.

#### **PROCEDURES FOR DISCLOSURE OF EXTERNAL FUNDING**

- When external funding supports presentations or awards at regional or annual meetings, the program for the meeting should indicate the sources and nature of external support. Speakers should disclose whether any part of their presentation resulted from external funding and whether they have any personal financial interest in the subject matter of the presentation.
- All externally funded research and educational projects will be posted on the SGIM web site by leaving the project descriptions, originally posted for member review and comment, on the site with an indication that funding was ultimately accepted for the project, as well as a brief paragraph summarizing the outcome of the review from the Chair of the Ethics Committee.
- The SGIM Treasurer will prepare an annual report on the sources and amounts of external funding (both at the national level and for each region) at the end of each fiscal year, along with a calculation of the proportion of the operating budget for the fiscal year derived from external funding. The report, when accepted by Council, will also be posted on the SGIM web site.

**Appendix 1. Calculating the proportion of the SGIM Operating Budget (for the current fiscal year) supported by external funding (non-member revenue).**

**THE EQUATION:**

Total dollars from the funder(s) / (Actual annual operating revenues plus contract offsets against expenses) = % of operating budget for the current fiscal year represented by that source

**EXAMPLES:** 1. SGIM receives a \$25,000 contribution from Alvinol Pharmaceuticals to support a Research & Education Mentorship Program. SGIM takes 10% overhead on awards, and “passes through” the rest to its member awardees. That year, SGIM’s actual revenues plus contract offsets in the operating budget total \$2,200,000.

In the equation... \$2,500 is the numerator. \$2,200,000 is the denominator. Divide, and the result is the percentage of the approved budget that is supported by this particular contribution. (= .1%)

2. The same year SGIM receives a \$50,000 grant from AHRQ to support an EBM workshop. SGIM has a federally negotiated overhead rate of 30%, providing an additional \$15,000. The \$50,000 for the project is put in a restricted fund to pay project expenses, and does not appear in the operating budget, while the \$15,000 overhead appears in the operating budget.

In the equation... \$15,000 is the numerator. \$2,220,000 is the denominator. Divide, and the result is the percentage of the approved budget that is supported by this particular contribution. (= .7%)

Source of External Funding per Fiscal Year	Cannot Support More Than:
Combined External Funding (all non-member revenue)	33% of SGIM’s operating budget
Combined Funding from Health Care-Related For-Profits	10% of SGIM’s operating budget
Single Health care-Related For-Profit	5% of SGIM’s operating budget
Single Non-health Care-Related For-Profit	15% of SGIM’s operating budget
Single Non-Profit	15% of SGIM’s operating budget

**Appendix 2. Template for proposals to SGIM for research or educational projects requiring SGIM's participation and external funding.**

**PROPOSAL FOR AN EXTERNALLY-FUNDED SGIM RESEARCH OR EDUCATIONAL PROJECT**

**COVER PAGE (limit: one page)**

Name of Principal Proponent (Must be an SGIM Member):

Contact Information for Principal Proponent (including fax number and email address):

Names and Institutions of Other Participating SGIM Members or Groups (Attach biographical sketches for the Key Project Personnel):

Title of Project:

Nature of Project: Research \_\_\_\_\_ Educational \_\_\_\_\_

SGIM's Proposed Role: Applicant Organization \_\_\_\_\_

Collaborator with Applicant Organization \_\_\_\_\_ (Provide name of applicant organization): \_\_\_\_\_

Date Submitted:

Proposed External Funder (Indicate whether Proposed Funder is a For-Profit Company, and whether the Proposed Project is in Response to a Request for Proposals from the Funder. If possible, provide an internet URL of the Call for Proposals from the Funder):

Due Date for Application to the Funder (if applicable):

**Principal Proponent Must Sign to Acknowledge the Following Statement:**

"I have read and familiarized myself with the SGIM Policy on Acceptance and Disclosure of External Funds. I believe the project I am proposing that requires external funding is acceptable according to the policy."

Signed: \_\_\_\_\_

## **DESCRIPTION OF PROJECT (limit: 3 pages)**

Project Objectives:

Methods:

Timetable:

Estimated Budget:

Brief Description of the Proposed Funder:

Brief Description of how the Project is:

- consistent with the SGIM mission, “To be the professional home for innovators and scholars in academic general internal medicine leading the way to better health for everyone”; and
- judged to be particularly well suited to be carried out by SGIM as an organization.

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*Note: This policy has evolved from the original SGIM Policy regarding Acceptance of External Funds, which was approved on January 6, 1994 and amended on December 3, 2000. It also subsumes two previous appendices to that document adopted February 10, 2000 and March 3, 2000. The policy underwent a mandated review and revisions were approved by the SGIM Council on December 8, 2005. The November 2018 amendment was for the purposes of addressing exhibits.*