

## *Summary of Recommendations*

### 56 Principles to Guide Academy-Industry Engagement

**T**he American Association of University Professors (AAUP) has drafted these principles to encourage universities and their faculties to adopt stronger, more comprehensive rules to guide sponsored research on campus and to manage individual and institutional conflicts of interest more effectively. In issuing this report, the AAUP seeks to ensure that the standards and practices it recommends are consistently applied across the university as a whole. The report contains 56 recommended principles. A majority (35) are closely drawn from previous statements issued by the AAUP or other prominent academic societies and associations (such as the Institute of Medicine, the Association of American Universities, and the Association of American Medical Colleges). The remainder are either adapted from these other associations, or are new recommendations which the AAUP is issuing for the first time. (Appendix B identifies which recommendations fall into each category, along with specific sources.)

The AAUP seeks to promote deeper awareness of how commercial relationships—though often highly beneficial—may have far-reaching consequences for the university, its missions, and its constituents (students, faculty, colleagues, patients, the public) as well as on the academic profession (in areas ranging from research integrity and reliability to knowledge sharing, public health, and public trust). Although the report focuses primarily on academy-industry relationships, it addresses government- and nonprofit-sponsored research when related and appropriate. Because students, graduate assistants,

postdoctoral fellows, and academic professionals often work on sponsored research, the report also addresses their working conditions.

To be effective, academic senates or comparable faculty governing bodies will need to review these 56 principles, adapt them as appropriate, and then recommend their adoption in faculty handbooks, university policy statements, faculty guidelines, or collective bargaining contracts. (Appendix A contains specific suggested policy language that faculty and administrators may employ or adapt in their own written policies and guidelines.) Whenever possible, faculty bodies will benefit from working cooperatively with knowledgeable university administrators to formulate clearer campus guidelines and protocols. Many administrators will be equally interested in developing clear campus guidelines that will provide greater clarity in negotiating agreements with potential sponsors.

**Contents:** The 56 principles recommended by the AAUP fall into two broad categories:

GENERAL PRINCIPLES, which may be applied university-wide, that cover core academic norms and standards, such as authenticity of authorship, publication rights, and academic autonomy; they also address broad areas of academy–industry engagement, such as student education and training, financial conflicts of interest, and intellectual property management, and

TARGETED PRINCIPLES that address specific types of academy–industry engagement, including strategic corporate alliances (SCAs), industry–sponsored clinical trials, and academy–industry interactions at academic medical centers.

Many of the principles that the AAUP recommends in this report apply to the university generally, not just to sponsored research. A faculty body reviewing these principles might begin by making certain that all relevant campus documents incorporate the fundamental positions on shared governance and academic freedom embodied in Principles 1 and 2, the reinforcement of academic publication and research and data rights in Principles 3 and 5, the protections for recruiting, impartial academic evaluation, and access to grievance procedures in Principles 8–10, the basic intellectual property guarantees in Principles 11–13, and the commitment to conflict of interest disclosure in Principle 22. Reaching consensus about these opening principles will inevitably trigger a continuing discussion of others.

At many institutions, adoption of the full set of intellectual property principles, numbers 11–21—principles that should cover all intellectual

property, not just IP generated by industry-sponsored research—would represent a significant change in recent campus culture. Indeed as universities and their campus administrations become increasingly interested in claiming the rights to faculty IP, the benefit of installing these principles in faculty handbooks and collective bargaining contracts is clear. The goal should be to include appropriate language in both institutional policy guidelines and in all university contracts for funded research.

Similarly, a comprehensive campuswide set of conflict of interest (COI) policies will require consideration of the entire COI subsection, numbers 22–31. Given that sponsored research and paid consultancies occur at all types of academic institutions, reviewing each institution’s existing COI policy statements and regulations—or establishing them, if none exist—should be a high priority. At the same time, Principles 36–47 are salient only for institutions that already have, or contemplate establishing, the large-scale, multi-year research partnerships known as strategic corporate alliances (SCAs). Principles 32–35 and 49–56 (addressing clinical research and conditions in academic medical colleges) are of primary interest to institutions with faculty members or academic units engaged in biomedical research and patient care.

A first step toward implementing these recommendations might be to have an AAUP chapter or a group of concerned faculty introduce a resolution in the faculty senate, or in a comparable campus governing body, to create a committee charged with comparing campus-based policies, practices, and regulations with this report’s recommendations. The committee would research and report on faculty-handbook recommendations, formal university policies, patent and licensing office protocols, and other campus guidance documents. At universities in which faculty engage in collective bargaining, some of the policies could be incorporated into union contracts. In all cases, committees would consult widely with diverse groups of faculty across disciplines and build broad-based consensus around these principles and the language recommended for the destination documents.

In formulating these principles, the AAUP inevitably recognized tensions between the ideal conditions we would like to promote and the realities of contemporary academy-industry relations. We therefore sometimes state a principle first in more ideal terms and then offer qualifications, recognizing the partial compromises that may be necessary. Some faculty, academic senates, administrators, and universities will want to strengthen certain of these 56 principles, while others may wish to weaken them or adapt them in other ways. We aim to strike a realistic balance in proposing them, one flexible enough to stand the test of changing conditions. The primary value of the principles is to reaffirm universities’ core academic and public missions,

uphold professional academic and research standards, and influence contract relationships yet to be written or up for renewal.

**Definition of a “significant” financial interest:** Throughout this report and the following Principles, the AAUP defines a financial interest to be “significant” if it is valued at or above \$5,000 per year, and it is not controlled and/or managed by an independent entity, such as a mutual or pension fund. This definition is consistent with the definitions and de minimis threshold for financial disclosure established by the US Department of Health and Human Services in its 2011 conflict of interest disclosure rules (*Department of Health and Human Services, DHHS, 42 CFR Part 50, 45 CFR Part 94, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” Federal Register, Vol. 76, No. 165, August 25, 2011, available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>*).

*The relevant sections of these DHHS rules are reprinted in full at the end of the Summary of Principles for easy reference. See pages 34-36.*

## **PART I—GENERAL PRINCIPLES & STANDARDS TO GUIDE ACADEMY-INDUSTRY ENGAGEMENT**

**PRINCIPLE 1—Faculty Governance:** The university must preserve the primacy of shared academic governance in establishing campuswide policies for planning, developing, implementing, monitoring, and assessing all donor agreements and collaborations, whether with private industry, government, or nonprofit groups. Faculty, not outside sponsors, should retain majority control over the campus management of such agreements and collaborations.

**PRINCIPLE 2—Academic Freedom, Autonomy, and Control:** The university must preserve its academic autonomy—including the academic freedom rights of faculty, students, postdoctoral fellows, and academic professionals—in all its relationships with industry and other funding sources by maintaining majority academic control over joint academy-industry committees and exclusive academic control over core academic functions (such as faculty research evaluations, faculty hiring and promotion decisions, classroom teaching, curriculum development, and course content).

**PRINCIPLE 3—Academic Publication Rights:** Academic publication rights must be fully protected, with only limited pre-publication delays (a maximum of 30–60 days\*) to remove corporate proprietary or confidential information, or to file for patents and other IP protections prior to

publication. Sponsor efforts to obstruct—or sponsored research agreements that do not permit—the free, timely, and open dissemination of research data, codes, reagents, methods, and results are unacceptable. Sponsor attempts to compel a faculty member, student, postdoctoral fellow, or academic professional to edit, revise, withhold, or delete contents in an academic publication (including a master’s thesis or PhD dissertation) or presentation (beyond legally justified claims to protect explicit trade secrets) must be clearly prohibited in all sponsored research contracts and university policies. A funder is of course free to make editorial suggestions, but academic researchers must be free at all times to accept or reject them.

*\*This time limit of 30–60 days for delays on publication (for the purpose of securing proprietary protection through a provisional patent or other IP filing) is consistent with recommendations issued by the National Institutes of Health, which are discussed in further detail in the main report.*

**PRINCIPLE 4—The Authenticity of Academic Authorship:** To protect the authenticity of academic publishing, universities and their affiliated academic medical centers should prohibit faculty, students, postdoctoral fellows, medical residents, and other academic professionals from engaging in industry-led “ghostwriting” or “ghost authorship.” Ghostwriting or ghostauthorship occurs when a private firm or an industry group initiates the publication of an “academic” article in a science or medical journal in support of its commercial products or interests, without publicly disclosing that the corporate entity has initiated and also often performed the initial drafting of the article, and then recruited an academic researcher (sometimes referred to as an “academic opinion leader”) to sign on as the nominal “author” (frequently in exchange for a fee). Although ghostwriting has been especially widespread in academic medicine, prohibitions on ghostwriting should be applied university-wide and should cover all faculty and researchers; the practice violates scholarly standards and is unacceptable in any academic setting.

**PRINCIPLE 5—Access to Complete Study Data and Independent Academic Analysis:** University codes of conduct should prohibit participation in sponsored research that restricts investigators’ ability to access the complete study data related to their sponsored research or that limits investigators’ ability to conduct unfettered, free, and independent analyses of complete data to verify the accuracy and validity of final reported results. Protecting access to complete study data is particularly important in the area of clinical research, where drug trials and other medical investigations are often conducted at multiple institutions simultaneously. If the sponsor

grants only partial access to the study's complete data sets or withholds other relevant research codes and materials, then the academic investigators and authors will not be able to perform a truly independent analysis of the study's data and outcomes. Universities should secure these basic academic freedom rights within the legal terms of all sponsored research contracts.

**PRINCIPLE 6—Confidential and Classified Research:** Classified research, as well as confidential corporate, government, or nonprofit research that cannot be published, is inappropriate on a university campus. Many institutions currently have written policies that ban classified government research on campus; the policies should be reviewed to ensure that they also ban confidential corporate research. Universities employ a variety of mechanisms for moving confidential and classified research off campus, sometimes using governance structures less subject to academic oversight. Sorting through multiple categories of “national security,” “classified,” and “sensitive but unclassified” (SBU) information requires expert monitoring by faculty governance bodies. These faculty bodies should operate with a strong presumption against permitting any confidential, classified, or non-publishable research on campus. Academic analyses and research results should always be publishable absent a compelling case to the contrary. This university commitment to knowledge sharing and openness should govern both the determination of which research will be confidential and thus cannot be performed on campus, as well as any rare exceptions that may be granted. As historical precedent suggests, the special circumstances of a formal congressional declaration of war against a specified nation-state or states may justify exceptions to the policies for the duration of the conflict.

**PRINCIPLE 7—Academic Consulting:** To address the potential for conflicts of commitment\* and financial conflicts of interest, all consulting contracts worth \$5,000 or more a year should be reported to the university's standing COI committee(s) charged with reviewing and managing both individual and institutional conflicts of interest (see Principle 24 for discussion of these committees). Neither faculty members nor administrators should sign a consulting contract that undercuts their professional ability to express their own independent expert opinions publicly, except when consulting with industry, government, or other parties on explicitly classified or proprietary matters. All such consulting agreements should be secured in writing.

\*A “conflict of commitment” arises whenever a faculty member's or administrator's outside consulting and other activities have the potential to interfere with their primary duties, including

*teaching, research, time with students, or other service and administrative obligations to the university.*

## **PART II—GENERAL PRINCIPLES TO GUIDE STUDENT EDUCATION AND TRAINING**

**PRINCIPLE 8—Recruiting and Advising Graduate Students, Medical Residents, and Faculty:** The admission of graduate students to degree programs and the appointment of medical residents and faculty should be based on their overall qualifications, not on their potential to work under a particular donor agreement or in a particular collaborative research alliance, whether commercial, governmental, or nonprofit. A PhD student's main advisor should be free of any significant financial interest, including equity, in a company that is funding or stands to profit from the student's thesis or dissertation research. Exceptions should evaluate both conflicts of interest and potential conflicts of commitment, all of which should be disclosed to all affected parties and periodically reviewed by an appropriate faculty body.

**PRINCIPLE 9—Impartial Academic Evaluation:** Students, postdoctoral fellows, academic professionals, and junior colleagues should always be entitled to impartial and fair evaluations of their academic performance. Because of the risk of both real and perceived bias, faculty members with a significant personal financial interest in the outcome of their students' research should not have sole responsibility for evaluating student progress toward a degree.

**PRINCIPLE 10—Grievance Procedures:** Universities should establish effective, well-publicized grievance procedures for all students, postdoctoral fellows, academic professionals, and faculty members, tenured and untenured, so they may freely and safely report obstacles encountered while pursuing their research and educational objectives. Obstacles may include but are not limited to inappropriate commercial or other sponsor influence over the conduct or analysis of research, unwarranted delays to degree completion, financial conflicts of interest, conflicts of commitment, and conflicts over ownership of intellectual property. Faculty with financial conflicts related to a grievance filing should recuse themselves from its adjudication in formal proceedings. Informal resolution of grievances is often preferable when possible.

### **PART III—GENERAL PRINCIPLES TO GUIDE MANAGEMENT OF INTELLECTUAL PROPERTY (IP)**

#### **PRINCIPLE 11—Faculty Inventor Rights and IP Management:**

Faculty members' fundamental rights to direct and control their own research do not terminate with a new invention or research discovery; these rights properly extend to decisions about their intellectual property—including invention management, licensing, commercialization, dissemination, and public use. Faculty assignment of an invention to a management agent\* (including the university that hosted the underlying research) should be voluntary and negotiated rather than mandatory, unless federal statutes or previous sponsored research agreements dictate otherwise. Faculty inventors retain a vital interest in the disposition of their research inventions and discoveries and should, therefore, retain rights to negotiate the terms of their disposition. Neither the university nor its management agents should undertake intellectual property decisions or legal actions directly or indirectly affecting a faculty member's research, inventions, instruction, or public service without the faculty member's/inventor's express consent. Of course faculty members, like other campus researchers, may voluntarily undertake specific projects under "work for hire" contracts.<sup>1</sup> When such agreements are truly voluntary and uncoerced, their contracted terms may legitimately narrow faculty IP rights.

*\*The term "invention management agent," as used in this report, covers all persons tasked with handling university generated inventions and related intellectual property, including, for example, university technology transfer offices, affiliated research foundations, contract invention management agents, and legal consultants.*

#### **PRINCIPLE 12—Shared Governance and the Management of University Inventions:**

Faculty have a collective interest in how university inventions derived from academic research are managed. Through shared governance, they have a responsibility to participate in the design of university protocols that set the norms, standards, and expectations under which faculty discoveries and inventions will be controlled, distributed, licensed, and commercialized. The faculty senate or an equivalent body should play a primary role in defining the policies and public-interest commitments that will guide university-wide management of inventions and other knowledge assets stemming from campus-based research. These protocols should devote special attention to the academic and public interest obligations covered in these principles. They should also require the formation of a specially assigned faculty committee to review the university's invention management practices regularly, ensure compliance with these principles, represent the interests of

faculty investigators and inventors to the campus, and make recommendations for reform when necessary.

**PRINCIPLE 13—Adjudicating Disputes Involving Inventor Rights:**

Just as the right to control research and instruction is integral to academic freedom, so too are faculty members' rights to control the disposition of their research inventions. Inventions made in the context of university work are the result of scholarship. University policies should direct all invention management agents to represent and protect the expressed interests of faculty inventors, along with the interests of the institution and the broader public. Where the interests diverge insurmountably, the faculty senate or equivalent body should adjudicate the dispute with the aim of promoting the greatest benefit for the research in question, the broader academic community, and the public good. Student and other academic professional inventors should also have access to grievance procedures if they believe their inventor or other intellectual property rights have been violated. Students should never be urged or required to surrender their IP rights in advance to the university as a condition of participating in a degree program.

**PRINCIPLE 14—IP Management and Sponsored Research Agreements:**

In negotiating sponsored research agreements, university administrators should make every effort to inform potentially affected faculty researchers and to involve them meaningfully in early-stage negotiations concerning invention management and intellectual property. In the case of large-scale sponsored research agreements like Strategic Corporate Alliances (SCAs), which can affect large numbers of faculty, not all of whom may be identifiable in advance, a special faculty governance committee should be convened to participate in early-stage negotiations, represent collective faculty interests, and ensure compliance with relevant university protocols. Faculty participation in all institutionally negotiated sponsored-research agreements should always be voluntary.

**PRINCIPLE 15—Humanitarian Licensing, Access to Medicines:**

When lifesaving drugs and other critical public health technologies are developed in academic laboratories with public funding support, universities have a special obligation to license such inventions so as to ensure broad public access in both the developing and the industrialized world. Exclusive university licenses to companies for breakthrough drugs or other critical public good inventions arising in agriculture, health, environmental safety, or other fields should include humanitarian licensing provisions that will

enable distribution of drugs and other inventions in developing countries at affordable prices whenever feasible.

**PRINCIPLE 16—Securing Broad Research Use and Distribution**

**Rights:** All contracts and agreements covering university-generated inventions should include an express reservation of rights—often known as a “research exemption”—to allow for academic, nonprofit, and government use of academic inventions and associated IP for non-commercial research purposes. Research exemptions should be reserved and well publicized prior to assignment or licensing so faculty and other academic researchers can share protected inventions and research results (including related data, reagents, and research tools) with colleagues at the host university or at any nonprofit or government institution. The freedom to share and practice academic discoveries—whether legally protected or not—for educational and research purposes is vital for the advancement of knowledge. It also enables investigators to replicate and verify published results, a practice essential to scientific integrity.

**PRINCIPLE 17—Exclusive and Nonexclusive Licensing:** Universities, their contracted management agents, and faculty should avoid exclusive licensing of patentable inventions, unless such licenses are absolutely necessary to foster follow-on use or to develop an invention that would otherwise languish. Exclusive or monopolistic control of academic knowledge should be sparing, rather than a presumptive default. When exclusive licenses are granted, they should have limited terms (preferably less than eight years), include requirements that the inventions be developed, and prohibit “assert licensing” or “trolling” (aggressively enforcing patents against an alleged infringer, often with no intention of manufacturing, marketing, or making productive use of the product). Exclusive licenses issued in order to permit broad access through reasonable and nondiscriminatory sublicensing, cross-licensing, and dedication of patents to an open standard may be expected to meet public access expectations. However, the preferred methods for disseminating university research are nonexclusive licensing and open dissemination, to protect universities’ public interest mission, open research culture, and commitment to advancing research and inquiry through broad knowledge sharing. To enhance compliance and public accountability, universities should require all invention management agents to promptly and publicly report any exclusive licenses issued, together with written statements detailing why an exclusive license was necessary and why a nonexclusive one would not suffice. The faculty senate or comparable governing body should periodically review exclusive licenses and corresponding statements for consistency with this principle.

**PRINCIPLE 18—Upfront Exclusive Licensing Rights for Research Sponsors:** Universities should refrain from signing sponsored research agreements, especially multi-year strategic corporate alliance (SCA) agreements, that grant sponsors broad title or exclusive commercial rights to future sponsored research inventions and discoveries—unless such arrangements are narrowly defined and agreed to by all faculty participating in, or foreseeably affected by, the alliance. If this is not feasible, as in the case of larger SCAs, the faculty senate should review and approve the agreement and confirm its compatibility with academic freedom, faculty independence, and the university’s public interest mission. All parties should consider the impact exclusive licenses could have on future uses of technologies. When granted, exclusive rights should be defined as narrowly as possible, restricted to targeted fields of use, and designed to safeguard against abuse of the exclusive position.

**PRINCIPLE 19—Research Tools and Upstream Platform Research:** Universities and their contracted invention management agents should make available and broadly disseminate research tools and other upstream platform inventions in which they have acquired an ownership interest. They should avoid assessing fees beyond those necessary to cover the costs of maintaining the tools and disseminating them, and avoid other constraints that could hamper downstream research and development. No sponsored research agreement should include contractual obligations that prevent outside investigators from accessing data, tools, inventions, and reports relating to scholarly reviews of published research, matters of public health and safety, environmental safety, and urgent public policy decisions.

**PRINCIPLE 20—Diverse Licensing Models for Diverse University Inventions:** Universities and their invention management agents should develop multiple licensing models appropriate to diverse categories of academic inventions, differing objectives and commitments made by faculty investigators and inventors, varying practices in the wider community and in different industries, and varied conditions that present at different stages in developing a technology. Licensing models commonly used to address opportunities in biotechnology, for example, should not be established as defaults in institutional policies or used indiscriminately across other areas of innovation. Faculty investigators/inventors and their management agents should work cooperatively to identify effective licensing and distribution models for each invention so as to enhance public availability and use. This may include established models (exclusive or nonexclusive licensing) as well as emergent ones (patent pools, open sourcing, and public licensing offered by institutions like Creative Commons for copyright-based work).

**PRINCIPLE 21—Rights to “Background Intellectual Property”**

**(BIP):** University administrators and their agents should not act unilaterally when granting sponsors’ rights to university-managed background intellectual property (BIP) related to a sponsor’s proposed research area but developed without the sponsor’s funding support. Universities should be mindful of how BIP rights will affect faculty inventors and other investigators who are not party to the sponsored research agreement. Nor should managers obligate the BIP of one set of investigators to another’s sponsored-research project, unless that BIP is already being made available under nonexclusive licensing terms, or the affected faculty members have consented. To do otherwise risks a chilling effect on collegiality and on faculty willingness to work with university licensing agents.

**PART IV—GENERAL PRINCIPLES TO GUIDE  
MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST  
(FCOI)**

*A conflict of interest (COI) is broadly defined as a situation in which an individual or a corporate interest has a tendency to interfere with the proper exercise of judgment on another’s behalf. Those who prefer to distinguish between individual and institutional COI often define the former as a set of circumstances creating a risk that a secondary interest, such as financial gain, may unduly influence professional judgment or actions regarding a primary interest, such as research conduct, teaching, or patient welfare. Correspondingly, an institutional COI occurs when the financial interests of an institution or institutional officials, acting within their authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other governing activities of the institution. A growing body of empirical research has shown that financial conflicts of interest (FCOI) are associated with decision making, as well as research, bias. (See the Introduction to this report for details.) FCOI may also introduce unreliability into the research process, undermine public trust, and erode respect for institutions of higher education. Disclosure of a COI, even full disclosure of a financial interest with informed consent, fails to resolve or eliminate such problems. However, it is critically important as a first step towards promoting transparency and awareness of the existence of COIs.*

**PRINCIPLE 22—Comprehensive COI Policies:** Every university should have a comprehensive, written COI policy, covering both individual and institutional COI. The policy or its accompanying guidelines should specify how all conflicts of interest (COI) and financial conflicts of interest (FCOI), in particular, will be reported, reviewed, managed, or eliminated. The guidelines should identify which FCOI must be reported, which are

prohibited, and what actions will be taken if faculty members do not comply with COI disclosure and management policies. Enforcement actions for non-compliance may include a faculty-led investigation leading to possible censure, federal-grant agency notification, a temporary hold on interactions with conflicted sponsors, or a temporary ban on receipt of outside research funding.

**PRINCIPLE 23—Consistent COI Enforcement across Campus:** University COI policies must be adopted consistently across the whole institution, including affiliated medical schools, hospitals, institutes, centers, and other facilities, and they must apply to faculty, students, administrators, and academic professionals.

**PRINCIPLE 24—Standing COI Committees:** Every university should have one or two standing COI committees to oversee implementation of policies addressing individual and institutional COI. At least one member should be recruited from outside the institution and approved by the faculty governing body. All committee members should be free of COI related to their oversight responsibilities. After faculty COI disclosure statements have been reviewed by an appropriate standing committee, they should be made available to the public, preferably on a readily accessible online database, as the AAUP recommends under Principle 31.

**PRINCIPLE 25—Reporting Individual COI:** Faculty members and academic professionals should be required to report to the standing campus COI committee all significant outside financial interests relating directly or indirectly to their professional responsibilities (research, teaching, committee work, and other activities), including the dollar amounts involved and the nature of the services compensated. The report must be made regardless of whether or not people believe their financial interests might reasonably affect their current or anticipated university activities. Faculty members should also report family member (spouse, partner, or dependent child) patent royalty income and equity holdings related to their own teaching and research areas. All administrators should report similar financial interests to both their superiors and the COI committee. Presidents and chancellors should also report to the standing committee.

**PRINCIPLE 26—Inter-office Reporting and Tracking of Institutional COI:** To keep track of institutional COI, every institutional COI committee should have a well-developed, campuswide reporting system that requires the technology transfer office, the office of sponsored programs,

the development office, the grants office, institutional review boards (IRBs), purchasing offices, and corresponding offices at affiliated medical institutions to report to the standing COI committee at least quarterly on situations that might give rise to institutional conflicts.

**PRINCIPLE 27—Strategies for Reviewing, Evaluating, and Addressing COI:** Disclosure of a COI is not a sufficient management strategy. The best course of action is not to acquire COI in the first place. Strategies for addressing *individual* COI include divesting troublesome assets, terminating consulting arrangements, resigning corporate board seats, and withdrawing from affected projects. Methods for addressing *institutional* COI include the institution divesting its equity interest in companies connected with campus research, placing conflicted equity holdings in independently managed funds, establishing explicit firewalls to separate financial from academic decisions, recusing conflicted senior administrators from knowledge of, or authority over, affected research projects, and requiring outside committee review or oversight. Some university presidents decline to serve on corporate boards to avoid the appearance of COI. Because of conflicting fiduciary responsibilities, campuses should prohibit senior administrators from receiving compensation for serving on corporate boards during their time in office.

**PRINCIPLE 28—Developing Formal, Written COI Management Plans:** If a university's standing COI committee finds compelling circumstances for allowing a research project or other professional activity to continue in the presence of a significant FCOI—without the elimination of the conflict—the committee should document the circumstances and write a formal management plan for each case. The plan should detail how the university will manage the FCOI and eliminate or reduce risks to its affected constituents (students, collaborating researchers, faculty, patients), its pertinent missions (research integrity, informed consent, and recruitment of research volunteers), and its reputation and public trust. This recommendation is consistent with the Department of Health and Human Services (DHHS) National Institutes of Health (NIH) rules implemented in 2011 to address financial conflicts, which require all universities that receive DHHS grants to prepare and enforce such management plans. (Those rules are partially reprinted at the end of the Summary of Principles.)

**PRINCIPLE 29—Oversight and Enforcement of COI Rules:** All university COI policies should have effective oversight procedures and sanctions for noncompliance. These are essential to ensure compliance with university rules and to sustain public trust in the university's ability to regulate itself.

**PRINCIPLE 30—University-Vendor Relationships and COI:** Universities should ensure that vendor evaluation, selection, and contracting for university products and services are consistent with their academic mission and do not jeopardize the best interests of students. Vendors should never be persuaded or coerced into making financial contributions to the university, either through direct university donations or recruitment of other contributing donors, in exchange for winning university contracts. All university bidding for contracts and services related to such areas as banking and student loans should be conducted through a fair, impartial, and competitive selection process. Many universities currently have ethics policies banning gifts from vendors; the policies should also clearly prohibit institutions from accepting direct remuneration, or kickbacks, from vendors doing business with the university or its students. Such profiteering can undermine public trust in the university and compromise the best interests of the students the university has pledged to serve.

**PRINCIPLE 31—COI Transparency: Public Disclosure of Financial Interests and COI Management Plans:** University COI policies should require faculty, administrators, students, postdoctoral fellows, and academic professionals to disclose to all journal editors all significant personal financial interests that may be directly or indirectly related to the manuscripts they are submitting for consideration. COI disclosure on publications should summarize all related funding sources received during the past five years, not simply for the project at hand. The same COI disclosure requirements should apply to oral presentations delivered in conferences, courts, and legislative chambers. After the university's standing COI committee reviews faculty conflict of interest disclosure statements, they should be posted to a publicly accessible website, and this information should remain accessible for at least ten years. This is important to address growing demands from Congress, state governments, journal editors, the media, and public interest groups for increased transparency and reporting of faculty COI. It is consistent with DHHS-NIH (2011) rules, which require universities to disclose all significant FCOI (as per the DHHS-NIH definition) related to a faculty member's DHHS-funded research on a public website or provide the information upon public request within five days. Disclosure of FCOI should also extend to affected patients and human research volunteers. (For details, see Principle 35).

## **PART V—TARGETED PRINCIPLES: MANAGING COI IN THE CONTEXT OF CLINICAL CARE AND HUMAN SUBJECT RESEARCH**

**PRINCIPLE 32—Individual and Institutional COI and Human Subject Research:** To maximize patient safety and preserve public trust in the integrity of academic research, there should always be a strong presumption against permitting FCOI related to clinical medical research and experimental studies involving human subjects. A “rebuttable presumption” against permitting clinical trial research that may be compromised by FCOI should govern decisions about whether conflicted researchers or institutions are allowed to pursue a particular human subject research protocol or project, unless a compelling case can be made to justify an exception.

**PRINCIPLE 33—Institutional Review Boards (IRBs) and COI Management:** An IRB should review all proposed human clinical trial protocols to identify all relevant FCOI before research is allowed to proceed. First, institutions should have clear policies, compliant with applicable federal regulations, to address reporting and management of FCOI associated with IRB members themselves. Policies should require conflicted IRB members to recuse themselves from deliberations related to studies with which they have a potential conflict. Second, the policies should require the institution’s standing COI committee to prepare summary information about all institutional and individual FCOI related to the research protocol under review. The summary should accompany the protocol when it is presented to the IRB. The IRB should take the COI information into account when determining whether and under what circumstances to approve a protocol. Neither the IRB nor the standing COI committee should be able to reduce the stringency of the other’s management requirements. The double-protection system is consistent with the two sets of federal regulations governing clinical research and provides appropriate additional safeguards for patient volunteers. Finally, if a research protocol is allowed to proceed, university policies should require disclosure of any institutional and investigator FCOI as well as the university’s management plan for addressing them to all patient volunteers (in informed consent documents) and all investigators and units involved with the research protocol.

**PRINCIPLE 34—COI, Medical Purchasing, and Clinical Care:** Academic medical centers should establish and implement COI policies that require all personnel to disclose financial interests in any manufacturer of pharmaceuticals, devices, equipment, or any provider of services and to

recuse themselves from involvement in related purchasing decisions. If an individual's expertise is essential in evaluating a product or service, that person's financial ties must be disclosed to those responsible for purchasing decisions.

**PRINCIPLE 35—COI Transparency in Medical Care:** University policies should require all physicians, dentists, nurses, and other health professionals as well as investigators, to disclose their FCOI to patients, human subject volunteers, and the broader public, unless those COI have been eliminated.

## **PART VI—TARGETED PRINCIPLES: STRATEGIC CORPORATE ALLIANCES (SCAs)**

*A Strategic Corporate Alliance (SCA) is a formal, comprehensive, university-managed research collaboration with one or more outside company sponsors, centered around a major, multi-year financial commitment involving research, programmatic interactions, "first rights to license" intellectual property, and other services. An SCA is frequently negotiated through a central university development office in tandem with a group of faculty, an entire academic department, or many different departments in unison. In broad SCA agreements, it is customary for universities, in each new grant cycle, to issue a formal request for faculty research proposals (RFP) on behalf of the outside corporate sponsor(s). In narrow SCA agreements, by contrast, all faculty members eligible for SCA funding and their projects are named and identified in advance, so a university-led RFP and research-selection process is not required.*

**PRINCIPLE 36—Shared Governance and Strategic Corporate Alliances (SCAs):** Faculty senates should be fully involved in the planning, negotiation, approval, execution, and ongoing oversight of SCAs formed on campus. The senate should appoint a confidential committee to review a first draft of a memorandum of understanding (MOU) pertaining to newly proposed SCAs. All parties' direct and indirect financial obligations should be made clear from the outset. Before an agreement is finalized on a broad SCA, the full faculty senate should review it. Formal approval of broad SCAs should await both stages in this process. All approved SCA agreements should be made available to faculty, academic professionals, and the public. If the SCA designates funding for new faculty appointments (FTEs), all normal university and departmental procedures for academic searches, hiring, and promotion decisions must be followed to honor and protect academic self-governance and academic freedom. Temporary employees should not exclusively staff,

administer, or supervise SCAs. Normal grievance procedures, under collective bargaining agreements where they exist, should govern complaints about interference with academic freedom or other academic rights that may arise under SCAs. In the absence of such procedures, grievances and complaints should be reported to the SCA faculty oversight committee (see Principle 47 for details) or to relevant college or university grievance committees for independent investigation. Standard safeguards regarding procedural fairness and due process must be respected and followed.

**PRINCIPLE 37—SCA Governance and Majority Academic Control:**

The best practice in any academy–industry alliance agreement—consistent with the principles of academic freedom, university autonomy, and faculty self-governance—is to build clear boundaries separating corporate funders from the university’s academic work. Yet the current conditions of increasingly close university–industry relations make erecting strict walls unrealistic on some campuses. Instead, at a minimum, universities should retain majority academic control and voting power over internal governing bodies charged with directing or administering SCAs in collaboration with corporate sponsors. The SCA’s main governing body should also include members who are neither direct stakeholders of the SCA nor based in academic disciplines or units likely to benefit from the SCA. A joint university–industry SCA governing body may have a role in awarding funding, but it should have no role in such exclusively academic functions as faculty hiring, curriculum design, course content, and academic personnel evaluation.

**PRINCIPLE 38—Academic Control over SCA Research Selection (for Broad SCAs):**

In the case of broad SCAs, university representatives should retain majority representation and voting power on SCA committees charged with evaluating and selecting research proposals and making final research awards. These committees should also employ an independent peer review process.

**PRINCIPLE 39—Peer Review (for Broad SCAs):**

Using a standard peer-review process, independent academic experts should evaluate and award funding whenever SCAs issue a request for proposals (RFPs) in a new grant cycle. Any expert involved in the peer-review and grant-award process should be free of personal FCOI related to the area of research being reviewed to insure that research selection is scientifically driven, impartial, and fair. Appointees to committees charged with research selection for a given SCA should be prohibited from awarding that funding to themselves,

their departments, or their labs, and should not be past recipients of funding from that SCA.

**PRINCIPLE 40—Transparency Regarding the SCA Research Application Process:** SCA agreements must clearly and transparently detail the methods and criteria for research selection and must explain how academic researchers may apply for SCA grants.

**PRINCIPLE 41—Protection of Publication Rights and Knowledge Sharing in SCA Agreements:** All the provisions of Principle 3 should apply to SCAs as well.

**PRINCIPLE 42—SCA Confidentiality Restrictions:** To protect the university's distinctively open academic research environment, restrictions on sharing corporate confidential information and other confidentiality restrictions should be minimized to the maximum extent possible in SCA agreements. To achieve this objective, sponsors should be discouraged from sharing confidential corporate trade secrets with their academic partners except when absolutely necessary. Such confidential information should ordinarily be disclosed to the smallest number of academic investigators possible, with strict supervision from the university's legal office to prevent corruption of the academic research environment.

**PRINCIPLE 43—SCA Anti-Competitor Agreements:** Anti-competitor or noncompete agreements compromise the university's academic autonomy, its ability to collaborate with other outside firms, and its commitment to knowledge sharing and broad public service. Restrictions in SCA agreements on faculty, academic professionals, postdoctoral fellows, and students interacting with or sharing information and research with private-sector competitors of SCA sponsors, or receiving separate research support from outside firms, should be avoided or minimized to the greatest extent possible.

**PRINCIPLE 44—Exclusive Licensing and SCA Agreements:** All the provisions of Principles 17 and 18 should apply to SCAs as well.

**PRINCIPLE 45—Limits on Broader Academic Disruption by SCAs:** Given the size and scope of many SCAs, a vigorous effort must be made to ensure that diverse areas of research—that pursue avenues of inquiry outside the purview of, not in conformity with, or even in opposition to the SCA's research agenda—are not crowded out and continue to enjoy institutional

support, resources, and sufficient financing. SCAs should be approved only if faculty and students within all academic units will, as a practical as well as a theoretical matter, retain the freedom to pursue their chosen research topics. SCA agreements should not disrupt the financial, intellectual, or professional arrangements of other academic units, colleges, and the university as a whole, and should avoid impact on faculty, academic professionals, postdoctoral fellows, and students engaged in research and activities outside the purview of the SCA. University policies should clearly affirm that no faculty member, postdoctoral fellow, academic professional, or student will be coerced into participating in a sponsored project; all participation must be entirely voluntary.

**PRINCIPLE 46—Early Termination of SCA Sponsor Funding:**

With any large-scale SCA, sponsors may threaten reduction or termination of funding or limits on funding in order to shape the research agenda or to express displeasure with its direction or findings. To reduce this risk, SCA contracts should include legally binding provisions to prohibit sudden, early termination of the agreement. If the negotiating process leads to inclusion of an early-termination option, it must prohibit the sponsor from arbitrarily or suddenly terminating the agreement or lowering pledged funding without at least three months advance notification. Salaries and research costs associated with the project must be continued for that period.

**PRINCIPLE 47—Independent, Majority Faculty Oversight of the SCA, and Post-Agreement Evaluation:**

An independent, majority faculty oversight committee consisting of faculty with no direct involvement in the SCA should be established at the start of a new SCA agreement to monitor and at least annually review the SCA and its compliance with university policies and guidelines. A post-agreement evaluation plan should also be included in the SCA contract so the campus can reflect and draw on the experience in organizing future campus-based academy-industry alliances. External evaluation may be appropriate for broad SCAs. Evaluation reports should be public documents.

**PRINCIPLE 48—Public Disclosure of Research Contracts and Funding Transparency:**

No SCA or other industry-, government-, or nonprofit-sponsored contract should restrict faculty, students, postdoctoral fellows, or academic professionals from freely disclosing their funding source. A signed copy of all final legal research contracts and MOUs formalizing the SCA and any other types of sponsored agreements formed on campus

should be made freely available to the public—with discrete redactions only to protect valid commercial trade secrets, but not for other reasons.

## **PART VII—TARGETED PRINCIPLES: CLINICAL MEDICINE, CLINICAL RESEARCH, AND INDUSTRY SPONSORSHIP**

**PRINCIPLE 49—Access to Complete Clinical Trial Data and the Performance of Independent Academic Analysis:** All the provisions of Principle 5 should apply to clinical trial data as well.

**PRINCIPLE 50—Registry of Academic-Based Clinical Trials in a National Registry:** Universities and affiliated academic medical centers should adopt clear, uniform, written policies to require all clinical trials conducted by their academic investigators to be entered into ClinicalTrials.gov (<http://www.clinicaltrials.gov/>)—the national clinical trial registry maintained by the US National Library of Medicine (NLM) and the National Institutes of Health (NIH). The entry should be made at or before the onset of patient enrollment. Entry in the register will help ward against manipulation of study results, suppression of negative findings, and improper altering of clinical trial protocols after the research has begun.

**PRINCIPLE 51—Safeguarding the Integrity and Appropriate Conduct of Clinical Trials:** All clinical trials affiliated with academic institutions should be required to use independent data safety monitoring boards (DSMBs) and/or publication and analysis committees to protect the integrity and appropriate conduct of academic-based clinical trial research.

**PRINCIPLE 52—Patient Notification:** No industry-, government-, or nonprofit-sponsored research agreement should restrict faculty or academic professionals from notifying patients about health risks or lack of treatment efficacy when such information emerges and patients' health may be adversely affected.

**PRINCIPLE 53—Undue Commercial Marketing Influence and Control at Academic Medical Centers:** Educational programs, academic events, and presentations by faculty, students, postdoctoral fellows, and academic professionals must be free of industry marketing influence and control. Both academics and administrators should be prohibited from participating in industry-led “speakers bureaus” financed by pharmaceutical or other industry groups. Institutions should also establish funding mechanisms for

clinical practice guidelines and high-quality accredited continuing medical education (CME) programs free of industry influence.

**PRINCIPLE 54—Appropriate Use of Facilities and Classrooms at Universities and Academic Medical Centers:** Universities, academic medical schools, and affiliated teaching hospitals should have clear and consistent policies and practices barring pharmaceutical, medical device, and biotechnology companies from distributing free meals, gifts, or drug samples on campus and at affiliated academic medical centers, except under the control of central administration offices for use by patients who lack access to medications. As a general principle, academic facilities and classrooms should not be used for commercial marketing and promotion purposes unless advance written permission from academic institutional authorities is explicitly granted and academic supervision ensured. (Commercial marketing of services would, for example, be appropriate at a job fair.) Campus policies should also require all marketing representatives to obtain authorization before site visits. Finally, faculty, physicians, trainees, and students should be prohibited from directly accepting travel funds from industry, other than for legitimate reimbursement of contractual academic services. Direct or indirect industry travel funding for commercial marketing junkets, which may include trips to luxury resorts and expensive dinners, should be prohibited.

**PRINCIPLE 55—Marketing Projects Masquerading as “Clinical Research”:** Faculty, students, postdoctoral fellows, and academic professionals based at academic-affiliated institutions must not participate in marketing studies that masquerade as scientifically-driven clinical trial research. Such thinly disguised marketing studies are frequently referred to as “seeding trials” because they are intended primarily to expose doctors and patients to newer, brand name drugs, not to uncover medically valuable or scientifically important insights.

**PRINCIPLE 56—Predetermined Research Results:** Faculty and other academic investigators should be prohibited from soliciting research funding from outside sponsors with the implied suggestion or promise of predetermined research results.

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**SIGNIFICANT FINANCIAL INTEREST:** Throughout this report we make use of the current Department of Health and Human Services definition. The DHHS rule defines a “significant” financial conflict of interest as

follows: “Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. . . . Significant financial interest means:

- (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:
  - (i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - (ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);  
or
  - (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution’s FCOI policy will specify the

details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

- (3) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; *income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles*; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education." [Emphasis added] (Source: Department of Health and Human Services, 42 CFR Part 50, 45 CFR Part 94, "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors," *Federal Register*, Vol. 76, No. 165, August 25, 2011, quotes on pp. 53283–84, available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf> )