APPENDIX

Checklist of Questions for Campus Leaders on Managing Individual Conflict of Interest

- 1. Who makes the decisions on individual conflict of interest cases on campus, at what level in the institution are they situated, and who is responsible for the oversight of this process? Through what channels does information about the cases and about the adequacy of the process go to reach the president/chancellor? What does this process look like in a flowchart?
- 2. How are faculty conflict of interest policies developed? Who holds ultimate authority over the policies: faculty senate, provost, president, trustees, state government? Are there separate policies, or separate implementation, in the medical center?
- 3. When a faculty member discloses a financial interest to an institutional official, as required, what happens next?
- 4. Are faculty members clear on what financial interests they need to disclose, to whom, and when?
- 5. Are there any sanctions for individuals who are required to report financial interests but do not? Have such individuals ever been discovered, and have sanctions ever been applied?
- 6. When financial disclosure identifies a potential conflict of interest, most such cases are handled on a case-by-case basis. What are the *tools* the campus uses to manage conflict of interest cases: disclosure to the research participants and possibly to the funding agency, divestment, monitoring, other means? What are the *criteria* that the campus uses to determine which of these tools should be employed? Which tools are most effective at measuring different types of conflict of interest? How have the last 10 cases

- where a conflict was identified been managed? Do federal regulations require an agency to be notified about any of these particular cases? If so, were they notified?
- 7. Is the IRB informed by the campus conflict of interest committee or official when conflicts of interest have been identified in an investigator's protocol review, and told how the conflicts are being managed? Do the IRBs require that prospective research participants be informed of investigators' related financial interests, if any? Are they informed of related institutional financial interests, if any. Are research participants informed in all cases, or only in some?
- 8. Are there campus policies in place regarding conflict of interest of members of any campus committees that review the research proposals (such as for IRBs, conflict of interest committees, and animal care committees)?
- 9. Are there rules governing whether companies in which the university has an equity stake—acquired through the university's technology transfer activities—can sponsor research at the university? Are there rules if the equity stake is acquired through investments from the university's endowment? If the company can sponsor research, can the principal investigator have an equity stake in the company?
 Can that individual be an officer of the company?
- 10. Are there any rules governing a group of faculty, such as those in a private practice plan, using their resources to purchase large equity positions in companies that directly relate to their area of research or clinical practice?

- 11. How is conflict of interest defined in the university's policies? Do the rules apply equally to faculty, administrators, and governing or university—controlled foundation boards?
- 12. Who oversees what the campus Office of Technology Licensing (OTL) does and how it interacts with research management and conflict of interest management? To whom does OTL management report? Who reviews the details of decisions made by the OTL on behalf of the
- university? How variable are its practices? Are there published guidelines that inform and bind the OTL's degrees of freedom?
- 13. Are there rules about trustee involvement (such as venture capitalists) in the commercialization of university/faculty intellectual property?
- 14. Are there coordinated data systems to track data and alert management where problems are developing and require follow-up?



ASSOCIATION OF AMERICAN UNIVERSITIES 1200 New York Avenue, NW, Suite 550 • Washington, D.C. 20005 tel 202.408.7500 • fax 202.408.8184 • web www.aau.edu