
Kelly Willenberg, lead editor, 2019, 205 pages, Health Care Compliance Association, $200

Review by Norman M. Goldfarb

“Research Compliance Professional’s Handbook, 3rd Edition: The Practical Guide to Building and Maintaining a Clinical Research Compliance & Ethics Program” distills the essential elements of a clinical research compliance and ethics program for anyone who wants to know how to govern, manage or work within a very complex area of responsibility.

The following excerpt from the chapter on financial conflicts of interest by Stuart Horowitz illustrates the straightforward nature of the book’s content:

A convenient paradigm with which to establish a set of rules consistent with institutional tolerance for risk is to categorize financial conflicts of interest (FCOI) in four ways. FCOIs may be thought of as: show-stoppers, garden-variety manageable, complex and custom. The first two categories are managed by rules and tools. The third requires deliberation based on principles.

Show-stoppers are FCOIs that the institution will not tolerate under any circumstances. A show-stopper is an FCOI that the institution feels cannot be managed or is not worth the risk of management. For these, either the FCOI is eliminated, or the research is disallowed. It goes without saying that any circumstance in which there is actual bias cannot be allowed. But these situations are few and far between, and much of the time, it boils down to whether the institution believes the appearance of bias is so strong and obvious that it is not worth the risk to try to manage it. These need not necessarily be lucrative opportunities for investigators. For example, many academic medical centers have decided that none of their faculty may participate on speakers’ bureaus — panels of paid experts who deliver public presentations on behalf of a pharmaceutical or medical device company.

The rules for show stoppers typically consist of a list of prohibited FCOIs. In addition to the speakers’ bureau rule, this list might include situations where:

- The value of the investigator’s remuneration or ownership is linked to the outcome of a study in which the investigator is participating.
- The investigator receives payment from the research sponsor while being unduly restricted from publishing the results of the research.
- The investigator has sole responsibility for data analysis for a study sponsored by a company in which he or she has a significant financial interest (as defined in the Final Rule or at a lower threshold if set by institutional policy).
- The investigator has sole responsibility for obtaining informed consent from research volunteers in a study involving a technology in which he or she has a significant financial interest.
- The investigator is the PI of a multicenter clinical trial at the institution, and is also a consultant to the sponsor, receiving $250,000 per year for providing services/advice.
There may be other FCOIs that an institution chooses to prohibit under all circumstances. In addition to listing them in the institution’s policies and procedures, it is useful to develop a set of SOPs that include flowcharts used as tools, instructing staff on how to determine if an FCOI falls into this category. It may also be possible to develop logic within software to assist in this process.

An FCOI can be categorized as garden-variety manageable if it meets a set of predetermined criteria. A garden-variety manageable FCOI is one that meets two broad criteria: First, it is typical or unremarkable. Second, it is one that the organization believes can be managed with a formal and (ideally) standard management plan. Note that an institution may adopt a policy that not every garden-variety FCOI can be managed, as in the case of the speakers’ bureau example. Membership on speakers’ bureaus is certainly typical and unremarkable (although these days, perhaps less so at academic medical centers). However, in some institutions, it does not meet the criteria for being manageable.

Some examples of garden-variety manageable FCOIs:

- Consulting for a company related to the investigator’s laboratory research but remunerated in an amount predetermined to be acceptable. For example, the institution can set policy that a consulting arrangement valued at no greater than $20,000 per year is an FCOI that can be managed.
- Conducting a clinical trial with a pharmaceutical company in which the investigator owns $25,000 in publicly traded stock. The institution can set a policy that ownership of up to $25,000 is an FCOI that can be managed.
- Advising a medical device company about the design of product in a multicenter clinical trial that the investigator is leading at one site. The institution can set a policy that payment to the investigator of up to $30,000 is an FCOI that can be managed.

In these examples, the upper limit of value may seem arbitrary. Ideally, however, the institution sets values reflecting its belief that they are acceptable because the appearance of bias is small, based partly on the amount, the investigator’s overall compensation, and the fact that the investigator is following a specific management plan. As suggested above, the institution can develop a small library of standardized, formal management plans for each garden-variety manageable FCOI. Each FCOI categorized in this way can be issued the appropriate standard management plan. For example, the investigator holding the stock may be issued a plan requiring that the prospective participant is informed of the ownership interest verbally and in writing, that all public presentations or publications emanating from the research include a predetermined ownership disclosure statement, and that the person obtaining informed consent is not the investigator.

As with show-stoppers, garden-variety manageable FCOIs can be identified and managed without committee deliberation. A clear set of standard operating procedures and flowcharts, managed by competent administrative staff or, in smaller institutions, by one staff member. It is also possible to automate a significant part of the process using dedicated FCOI software. This approach, backed up by quality assurance, can handle the bulk of FCOIs that require management plans.

The book includes 15 chapters by 24 contributors:

1. Research Compliance 101
2. Options for Identifying and Managing Financial Conflicts of Interest in Research: Flexible Compliance with the PHS Final Rule
3. Scientific and Research Misconduct
4. Biosecurity, Biosafety, and Biorisk Management
5. The Regulation of Research Using Animals
6. The Regulation of Research with Human Subjects
7. FDA-Regulated Clinical Research
9. Research Records Management
10. Data and Safety Monitoring
11. Clinical Research Billing Compliance
12. Grant Management
13. Research Auditing and Monitoring
14. What are Export Controls?
15. Integrating Research Compliance into the Corporate Compliance Program

Reviewer
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