

Implementation of Harvard Medical School Revised Conflicts of Interest Policy

Effective January 1, 2011, Harvard Medical School (HMS) adopted far reaching changes to its Conflicts of Interest Policy (the "Conflicts Policy") following a comprehensive review of the Conflicts Policy in light of the evolving relationship between the life science industry and academia. Those changes to the Conflicts Policy that impact industry's relationship with HMS faculty and what life science companies should do to address such changes were examined in Fabbri Law's article [here](#).

The changes to the Conflicts Policy that are relevant to life science companies fell into four basic categories:

- (1) requiring public disclosure of financial interests between faculty and life science companies,
- (2) lowering the annual compensation a faculty member can earn from a life science company when participating in research related to that company's interests,
- (3) introducing "wash-out" periods before (A) clinical research can be conducted following a consulting or similar arrangement, and (B) a consulting or similar arrangement can be entered into following clinical research, and
- (4) prohibiting the participation in speakers' bureaus or the receipt of gifts and most travel and meals.

HMS has provided additional guidance regarding the implementation and interpretation of its revised Conflicts Policy as described below.

Disclosure of Financial Interests with Industry

HMS is still working to consolidate its reporting requirements among itself and its affiliated institutions. HMS expects the requirement for its faculty members' financial interests in or from life science companies to be publicly disclosed to **begin the 2012/2013 reporting cycle**.

Reduction in Allowable Compensation from Industry

The income that an HMS faculty member may receive from a life science company for which he or she is participating in clinical research was reduced from \$20,000 to \$10,000 per year **effective April 1, 2011**. HMS faculty members having existing agreements that have the potential for payments greater than or equal to \$10,000 in 2011 may be honored, subject to review, for payments up to \$20,000, but will be subject to the \$10,000 limit in 2012 and beyond.

Washout Periods

The washout periods requiring that an HMS faculty must (i) be free of impermissible financial interests (other than an equity interest) for at least six months prior to commencing clinical research and (ii) not have participated in clinical research for at least 12 months prior to entering into a consulting arrangement, both become **effective July 1, 2011**. Participation in clinical research will be deemed to have ended as of the later of (A) 12 months following the last day a human participant completes the clinical trial or (ii) the first publication of trial data or the decision not to publish trial data.

Gift/Meal and Speaker Bureau Ban

The ban of gifts/meals and participation in speakers' bureaus becomes **effective July 1, 2011**. It is important to note that the gift ban is broader than the Massachusetts Gift Ban law¹ because it applies not

¹ M.G.L. ch. 111N

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only to clinical faculty at HMS, but all HMS faculty, including research scientists, fellows and post-docs. The ban on gifts and meals does not prohibit:

- (1) meals provided to faculty members while attending Scientific Advisory Board or Board of Directors meetings where attendance is required as part of a bona fide consulting agreement, provided the meal is served during the meeting and is modest in nature;
- (2) registration or travel fees for a professional or trade meeting where the student, fellow or faculty member is a speaker or panelist; or
- (3) "Users Group" meetings or training sessions to learn how to use a technical device that has been purchased by an HMS institution, where the attendance at the meeting or training session was included as part of a written contract.

HMS intends to issue additional guidance regarding speakers' bureaus and the intellectual independence of presentations and talks in the future.

William Fabbri
617-875-7190
wfabbri@comcast.net

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Because of the generality of this update, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on the particular situation.