



Outside Activity Report: What Do I Need to Report?

What Is This and Why Must I Do It?

- **All** HMS Faculty and Investigators (including post-docs) are required to annually certify all outside activities and financial interests, as well as the acquisition or discovery of a new outside activity within thirty days.
 - The HMS Policy on Conflicts of Interest and Commitment (COI) which requires annual reporting to ensure transparency and impartiality in all faculty activities.
 - New federal regulations became effective in August 2012 that require annual reporting for those involved with PHS-funded research.
 - Public trust in academic medicine and its continued legitimacy requires transparency.

Does This Mean Outside Activities Are Discouraged?

Absolutely not!

- Translation of knowledge and innovative technology from academia to the public requires increased collaboration between faculty and outside entities.
- HMS supports and encourages these interactions.

Engaging in reportable outside activities does not signify that you have done anything wrong or unethical.

What Am I Required to Report?

- **ALL outside** professional income, uncompensated activities, royalties and equity holdings **relevant to your institutional role**.
 - HMS has a **zero** dollar reporting threshold. This means that you must report **ALL** relevant outside activities, including those for which you do not receive compensation.
 - You must include relevant interests held by your partner/spouse and your dependent children (family).
- **Not Just Conflicts.** The reporting requirement is independent of whether your financial interests represent potential, perceived or actual conflict of interest.
- **Entity Reporting.** You are required to report each entity with which you have an outside relationship and/or a financial interest.

Is Anything Excluded from Reporting?



Yes!

You **do not** have to report:

- Financial interests or uncompensated activities from a charitable institution of higher education located in the United States.
- Financial interests in or uncompensated activities with federal, state or local government agencies (U.S.).
- Sponsored research support to HMS or an affiliated institution.
- Salary support or other income paid by HMS, an affiliated institution or any other academic teaching hospital, medical center, or a research institute that is affiliated with a charitable institution of higher education (U.S.).

UNLESS...

Payments from above are made on behalf of a commercial entity that would otherwise be disclosed.

What Is Relevant?



- You must report relationships with and financial interests in **pharmaceutical, device, biotechnology, and medical education and communication companies.**
- If you have any questions about what else needs to be reported, keep in mind the following:
 - Report any relationship that relies upon the experiences and professional expertise that serve as the basis for your faculty appointment.



Examples of Relevant Activities

Any relationship with an individual or entity that:

- Conducts **biomedical research**.
- Produces, provides or markets **medical services**, tools, devices, or products.
- Produces, provides or markets **research services**, tools, devices, or products.
- Prepares and/or publishes **biomedical journals**, **textbooks** or other **educational materials**.
- **Advocates** for or on behalf of physicians, researchers, patients and/or academics.

Examples of Relevant Activities (Continued)

Any relationship with an individual or entity that:

- Coordinates, manages, designs or otherwise assists in the delivery of **continuing medical education** (accredited or non-accredited) in any format.
- Advises individuals in connection with legal proceedings that require the **expert opinion** of a physician, researcher or academic.
- Engages in **any other activities** that are relevant to one's role as a physician, professor, researcher, supervisor, laboratory manager and/or administrator at HMS or an affiliated institution.

What Interests Must I Report?



Income. All income received by you or your family from a relevant entity. This includes:

- **Consulting fees or Salary.**
- Compensation for serving on a **Scientific Advisory Board.**
- Compensation for serving as a **Member of a Board of Directors.**
- Compensation for serving on a **Data Safety Monitoring Board.**
- **Honoraria** from industry, medical education and communication companies, providers of medical education and any other entity on whose behalf you give a scientific or medical presentation.

What Interests Must I Report?



(Continued)

Equity. Includes stock, stock options, warrants or similar ownership interest in entities relevant to your institutional role.

- **Does not** include:
 - Stock held in mutual funds, pensions, institutional investments, or other investment vehicles where you have no ability to control what shares you buy and sell.
- Includes all equity held by you and your family.
- Public Equity Valuation: You should report the value assigned by the entity in the year end or fourth quarter brokerage account statement.

What Interests Must I Report?



(Continued)

Royalties.

- Includes income earned from a relevant entity for the licensing of any intellectual property.
- You must report both royalties received directly from an independent entity and income from the institution(s) with which you hold a professional and/or academic appointment under its royalty sharing policy.

What Interests Must I Report?



(Continued)

Uncompensated Activities. Any relationship with an entity that would otherwise be reported, but for which you received no compensation.

- This may include:
 - Voluntarily advising a pharmaceutical company in the development of patient educational materials.
 - Volunteering as a subject matter expert for a healthcare advocacy group.
 - Volunteering to sit on the board of directors of a non-profit healthcare foundation.

Who Will See My Annual Outside Activities Report?



- The Office for Professional Standards and Integrity at HMS and liaisons at Harvard's Affiliates will have access to your report to ensure compliance with institutional rules.
- Additionally, your supervisors and/or Chair may be provided with your report.
- HMS will also compare your report with information available on public websites to identify common reporting errors and to provide ongoing education.

Questions?

If you have any questions, please do not hesitate to call us at 617-432-1343 or email us at outside_activities@hms.harvard.edu.