COMPARISON BETWEEN CONFLICT OF INTEREST POLICIES OF PRIVATE UNIVERSITIES

J. Jaya Murthy[1]

Any organization funding research at a University needs to be aware of any conflicts of interest that the faculty members or researchers conducting the research may have. Also, the ownership of any intellectual property created in a private university with funding from the federal government agencies vests directly with the university, rather than the individual faculty member or researcher.

The funding federal government agencies National Institute of Health[2] (NIH) mandate that investigators (faculty member / researcher) disclose to an official(s) designated by the institution, a listing of Significant Financial Interests (and those of his / her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding. The National Science Foundation[3] (NSF) also requires that grantee institute employing more than fifty persons to maintain an appropriate written and enforced policy on conflict of interest. The NIH policy has been effective from October 1, 1995. The NSF policy has been effective from July 1, 2002.

The reason for having these policies is to ensure that the funded research would not be compromised or biased by any conflicting interest or financial interest of those

[1] M.I.P. Candidate, 2007, Franklin Pierce Law Center, Concord, New Hampshire; Ph.D. University of Mumbai, India. Worked with GE-JFWTC as Intellectual Property Analyst and Thomson Derwent Scientific as Analyst.
[2] *NIH GUIDE*, Volume 24, Number 25, July 14, 1995
[3] *NSF* 02-151 July 2002, section 510.

investigators responsible for the research. There are two distinct areas of conflict[4]: conflict of interest and conflict of commitment.

A Conflict of Interest arises when a faculty member or his/her family or any Associated Entity possesses a financial interest in an activity which involves his/her responsibilities as a Faculty Member. A Conflict of Commitment arises when the faculty member / researcher has external activities that may interfere with discharging his/her responsibilities towards the University. These responsibilities include teaching, research, student training, class handouts etc.

The broad guidelines for the policies have been laid out by NIH[5] and NSF[6]. But what are the various clauses that need to go into these policies so as to adhere to these guidelines? This paper tries to answer this by comparing, contrasting and critiquing the policies of some prominent New England private Universities. Finally, a set of clauses for an ideal conflict of interest policy are discussed. An overview of the clauses is discussed in the paper as it is not possible to go into in-depth analysis of every clause. The paper is divided into three sections:

A. Common clauses present in the policies of all of the selected Universities;

B. Unique features among the policies of the Universities; and

C. Steps for drafting an ideal Conflict of Interest policy.

The private New England Universities selected for the study are listed below:

---

[4] See *On Preventing Conflicts of Interest in Government-Sponsored Research at Universities*, a Joint Statement of the Council of the American Association of University Professors and the American Council on Education (1964*); Managing Externally Funded Programs at Colleges and Universities*, especially "*Principle X. Research Ethics and Conflicts*", issued by the Council on Government Relations (1989); *Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research*, issued by the Association of American Medical Colleges (1990); and *Framework Document for Managing Financial Conflicts of Interest*, issued by the Association of American Universities (1993).

[5] *NIH GUIDE*, Volume 24, Number 25, July 14, 1995

[6] *NSF* 02-151 July 2002, section 510.

1. Boston College
2. Boston University
3. Brown University
4. Dartmouth
5. Harvard
6. Children's Hospital (Harvard)
7. Massachusetts Institute of Technology (M.I.T.)
8. Yale

This paper is meant to be a resource for any University / College interested in drafting a Conflict of Interest policy that satisfies the NIH and NSF funding policy requirements.

A. Common clauses present in the policies of all of the selected Universities.

All the Conflict of Interest policies of the selected Universities followed the guidelines set forth by NIH[7] and NSF[8]. All these policies were based on: defining the conflict of interest; the individuals to whom the policy would be applicable to; and in some cases conflict resolution. All the Universities require their employees (researchers / faculty members) to sign the conflict policy either at the time of accepting employment or when entering into a funded program.

All the University policies have a definition section where the terms used are described and defined. These definitions are consistent with those laid down by NIH / NSF. Such conflicts are handled by the General Counsel in most of these Universities.

[7] *NIH GUIDE*, Volume 24, Number 25, July 14, 1995
[8] *NSF* 02-151 July 2002, section 510.

Boston College[9] has a comprehensive policy, along with examples of activities that lead to potential conflicts which could arise during the course of employment. To make these policies more effective, the policies are applicable after a threshold amount. The faculty / researcher with a financial interest of value of $10,000 or more or represents more than 5% ownership interest are required to sign the policy.

All these Universities have a set process in place for effective implementation. For example, in Boston University[10], three steps are to be followed:

1. First, a full disclosure of individual interests that might conflict with the best interests of the University.
2. Second, the interested trustee, officer, employee or other representative must refrain from participating in University decision making with respect to any transaction or relationship in which he or she is interested.
3. Third, an independent determination must be made that the transaction or relationship meets the applicable standard and should be entered into or continued.

However, even when there are processes in place, conflicts can occur. How can such conflicts be resolved? Every University has a way of dealing with these conflicts by having a conflict management system in place. Brown University[11] does this by:

1. Monitoring of research by independent reviewers
2. Public disclosure of significant financial interests
3. Monitoring student relationships
4. Modification of the research plan

[9] See http://www.bc.edu/research/osp/policies/conflict.html
[10] See http://www.bu.edu/ethics/conflict.pdf
[11] See http://research.brown.edu/policies/coidisclosure.php#VI

5. Disqualification from participation in the portion of sponsor-funded research or the related business interest that would be affected by the significant financial interest Divestiture of significant financial interest
6. Severance of relationships that create actual or potential conflicts

The conflict of commitment is resolved by these Universities by including clauses that clearly define the terms and conditions of service. Boston College[12] resolves these by stating that Service as a consultant to outside organizations, provided that the time commitment does not exceed the then existing University policy, and that the arrangement in no way alters the faculty member's commitments incurred in the University's execution of a sponsored agreement on the faculty member's behalf.

Once a research project is funded, the outcome is usually in the form of IP that is generated. If this IP is in the form of patents, then Bayh-Dole Act[13] universally applies. Any copyrightable work that results would be subject to Copyright laws[14]. The University is left facing the issues of royalty and royalty sharing. All the Universities have a royalty clause in their policy to protect the interests of University and the faculty / researcher.

B. Unique features among the policies of the Universities

The Universities have a conflict of interest policy in place. However, each of these Universities has a unique feature in their policy, which makes the study of these policies an interesting study.

[12] See http://www.bc.edu/research/osp/policies/conflict.html
[13] 35 U.S.C. § 202.
[14] 17 U.S.C. §§ 101, 201(b).

M.I.T. has a unique Intellectual Property and conflict of commitment policy[15]. The Intellectual Property policy discusses the following:

1. Relationship of current policy with traditional faculty authorship rights (e.g. textbooks)
2. Criteria for ownership: scope of employment, resources used
3. Resource use criteria and/or definition
4. Revenue sharing formula
5. Administration of the policy

The conflict of commitment policy takes into account the open courseware and other commitments the M.I.T. may have, which is a unique feature of this University:

1. Requirement to disclose and permission process
2. Determination if faculty can teach courses, create courseware for other institutions
3. Determination if faculty can commercialize course content
4. Definition of how the name of the institution and faculty affiliation can be used

The other interesting clause that M.I.T. [16] and Brown University[17] have is technology licensing and equity ownership. These clauses are especially useful when the faculty member / researcher are in a managerial position. Conflicts most commonly arise when a new company licenses M.I.T. intellectual property, but can also occur when M.I.T. intellectual property is not involved.

[15] See http://web.mit.edu/committees/ip/ahip.policy.comparison.pdf
[16] See http://web.mit.edu/policies/4.4.html
[17] See http://research.brown.edu/policies/coidisclosure.php#V

M.I.T. has also conducted an interesting comparison study for IP policies and conflict of commitment policies between some of the leading Universities[18].

Dartmouth[19] has an interesting clause defining what to do when dealing with employment of relatives/nepotism in this manual. Dartmouth also enforces compliance with the conflict policies. Non-compliance can result in the following:

1. Formal admonition,
2. A letter from the appropriate Dean to the person's file,
3. Ineligibility for (i)grants, (ii)IRB approval, (iii) supervision of graduate students,
4. Non-renewal of appointment,
5. Dismissal.

Boston College[20] also has an interesting IP policy which gives details of what happens for the IP generated during the course of sponsored research. Patents, copyrights and combinations of IP generated are covered.

Boston College[21] and Boston University[22] have a concise Conflict Disclosure form, which take in account various conflicts that can arise due to an external funding situation. The form asks for disclosure from faculty / researcher about their and their immediate family; if they have or propose to have a business or financial relationship (as defined in the policy) with Boston University, either directly or through another entity in which they or their family member has a significant interest; the dollar value of this relationship; and nature of the relationship. Such disclosures help in the effective tracking of potential and real conflicts and helps in conflict resolution.

[18] See http://web.mit.edu/committees/ip/ahip.policy.comparison.pdf
[19] See http://www.dartmouth.edu/~hrs/pdfs/Conflict_Interest.pdf
[20] See http://www.bc.edu/research/osp/policies/conflict.html
[21] See http://www.bc.edu/research/osp/policies/conflict.html
[22] See http://www.bu.edu/ethics/conflict.pdf

The novel feature of Harvard[23] is that they have separate conflict policies for Medical School/Public Health School[24] and all other schools. These are managed by the Office of Sponsored Programs. The separate policies take into account the different conflicts that can arise when dealing with human beings and clinical research. The Vice President of Research Administration and the Associate General Counsel review forms that indicate potential conflicts to determine the information needed and who will speak with the faculty member. If information indicates a conflict that affects a clinical trial, the Director of Clinical Research Compliance gets involved. After information has been obtained, the Vice President of Research Administration and the Associate General Counsel determine whether a conflict exists and, if so, how to address it.

Harvard also has a separate conflict policy[25] for licensing inventions or other technology to for-profit companies. The University established conflict of interest policies and procedures for identifying, protecting and licensing innovations resulting from University activities. The University Office of Technology Development (OTD) and the Harvard Medical School Office for Technology Licensing and Industry-Sponsored Research (OTL) have been charged with responsibility for carrying out these policies under the oversight of the University's Committee on Patents and Copyrights.

Yale[26] has separate provisions in the conflict of commitment policy requiring faculty / researcher to put in their best efforts / minimum proposed effort while executing the responsibilities of their job. As a recipient of sponsored awards, the University

[23] See http://vpf-web.harvard.edu/osr/proposal/prop_pr_certifications.shtml#conflict
[24] See http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_101_002_coord_investigation.doc
[25] See http://www.techtransfer.harvard.edu/COIpolicy.html
[26] See http://www.yale.edu/ppdev/policy/1316/1316.pdf

assures sponsors that the effort expended on sponsored projects would be at least commensurate with the salary charged to those projects. In addition, sponsors are assured that uncompensated effort committed to a project would be provided.

Every University has included a special clause in their conflict of interest policy to best suit the University Mission and the type of research conducted.

C. Steps for drafting an ideal Conflict of Interest policy.

The policy clauses should reflect the NIH and NSF requirements for federal funded programs. The policy requirements differ based on the type of work or research that happens in the University / College and the individual University missions. The clauses that need to be included towards drafting an ideal conflict of interest policy are discussed below. The resources used to arrive at the following listing of clauses have been cited in the previous sections. These have also been listed in the Appendix[27].

1. The policy must be based on Financial Interest and the conflict that the Primary Investigators (faculty member / researcher) may have while conducting the sponsored research. The clause should include the financial interests of the Primary Investigator's immediate family.
2. Definitions of terms in the policy consistent with the NIH / NSF policies, for example who the Primary Investigator is etc.
3. Conflict of Commitment that the Primary Investigator may have while delivering towards his/her responsibilities of their job. The clause should include 'Best

[27] See *Appendix*.

efforts' language, specifying that the Principle Investigator put in his best efforts while conducting the research and defining the terms and conditions of service.

4. Procedural steps to effectively implement the conflict of interest policies. This process should include voluntary disclosure of all potential conflicts in a Conflict Disclosure form. This information should be well documented.
5. An effective conflict management system to ensure that conflicts are resolved in a quick and fair manner. This information should be well documented.
6. Technology transfer and licensing clauses effective to protect both the University as well as the Primary Investigator's rights. These clauses should take into account both licensing-in and licensing-out.
7. Clear terms of Royalty and Royalty sharing between University and Principle Investigator. It would be effective to have a formula defining the percentage share. For example, the share between the University and the Primary Investigator.
8. An Intellectual Property Policy that defines policies on Patents, Copyrights and use of University's trademarks. It is important to recognize that these rights are subjected to NIH / NSF guidelines.
9. Approvals for Primary Investigators before starting a new business/financial relationship are useful to ensure no conflict between the new funded research and the existing research conducted by the Primary Investigator.
10. If the University is engaged in Biotechnology or Clinical Trials, separate policies should be drafted to take into account the conflicts that can arise when dealing with human beings and clinical research.

Conclusion

An attempt has been made to make a comprehensive list of steps that go into drafting clauses for an effective Conflict of Interest policy that satisfies the NIH[28] and NSF[29] funding policy requirements. This paper is meant to be a resource for any University / College interested in drafting such a Conflict of Interest policy.

[28] *NIH GUIDE*, Volume 24, Number 25, July 14, 1995
[29] *NSF* 02-151 July 2002, section 510.

Appendix

- NIH:

http://grants.nih.gov/grants/guide/notice-files/not95-179.html

- NSF:

http://www.nsf.gov/pubs/2002/nsf02151/gpm5.jsp#510

- Boston College:

http://www.bc.edu/research/osp/policies/conflict.html

- Boston University:

http://www.bu.edu/ethics/conflict.pdf

- Brown University:

http://research.brown.edu/policies/coidisclosure.php#VI

- Dartmouth:

http://www.dartmouth.edu/~hrs/pdfs/Conflict_Interest.pdf

- Harvard

http://vpf-web.harvard.edu/osr/proposal/prop_pr_certifications.shtml#conflict

- Children's Hospital (Harvard):

http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_101_002_coord_investigation.doc

- MIT:

http://web.mit.edu/policies/4.4.html

- Yale:

http://apps.business.yale.edu/ppdev/transform.jsp?xml=xml/ppdev.xml&xsl=type_alpha.xsl&arg1=Policy&arg2=Policies&arg3=id