Guidelines for Institutional and Investigator Ownership of Equity, Managing Equity Obtained in the Transfer of Hospital Owned Technology in Companies Sponsoring Clinical Research

Policy

Introduction

Since 1993, when Children's Hospital first established guidelines ("the 1993 Guidelines") for accepting equity in companies that license its inventions and other technology, the Hospital has found that an equity position is, from time to time, a necessary and appropriate part of a strategy to translate a particular new medical discovery into a device, diagnostic or therapy that benefits the public. Taking equity in companies to which the Hospital transfers technology, however, may raise serious questions of conflicts of interest, as does investigator ownership of equity, whether directly, or beneficially through a share in institutional proceeds.

Generally, the decision to accept such institutional equity, and its management, are matters addressed by the 1993 Guidelines, this policy provides background on institutional and Harvard Medical School policies, and then sets forth the policy of the Committee on Clinical Investigation concerning how to address conflicts affecting the protection of human subjects in clinical research.

The 1993 Guidelines, as applied to clinical research

The 1993 Guidelines anticipated that the Hospital may participate in clinical trials sponsored by a company in which the Hospital holds stock, but prohibit the inventor of a test article from directing the clinical trial, whether directly or through supervision of the principal investigator. The 1993 Guidelines also state that, in deciding whether to participate in a clinical trial sponsored by a company in which the Hospital owns equity, the Hospital will take steps to effectively address
(1) patient safety;
(2) the validity and integrity of the data generated from the clinical trial;
(3) disclosure to the CCI in order that the IRB can determine, among other things, in what manner and to what extent such information should be shared with patients and others;
(4) ensuring that inappropriate preferential access to patient populations is not provided to companies in which the Hospital owns equity.

The 1993 Guidelines require the institution to preserve freedom to report research results, and to apply the same protective policies that would apply if there were no such equity interest. Specifically, a sponsoring company is allowed limited advance review of a substantially complete manuscript; the limited right to remove only its own confidential information (exclusive of such results), revealed to the author/inventor as such under the terms of a confidentiality clause in a license or sponsored research agreement; and no right to alter or otherwise delay the reporting of the research results.

Harvard Medical School Policy

Harvard Medical School's "Policy on Conflict of Interest and Commitment" prohibits full-time and part-time members of the faculty from:

> (a) participating in clinical research on a technology owned by or contractually obligated to a business in which the faculty member, a member of his/her family, or an associated entity has a consulting relationship, holds a stock or similar ownership interest, or has any other financial Interest, other than receipt of University or Hospital supervised sponsored research support or royalties under institutional royalty-sharing policies.
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> (b) receiving University or Hospital supervised sponsored research support (whether in dollars or in kind) for clinical research, or research which does not involve human subjects, from a business in which he/she, a family member, or an associated entity holds a stock or similar ownership interest.

Although there are certain de minimis exceptions, including for holding unrelated publicly traded equity for the second prohibition (b), one effect of the Policy is to bar a researcher from conducting or participating in clinical research on a technology, whether a drug, a device or a biological, that is licensed to, or owned by, any company in which an investigator hold any equity whatsoever. Recent clarifications by Harvard Medical School establish that this Policy would be violated even if the investigator's equity interest is a beneficial right to a distribution of institutionally-held equity, or proceeds from such equity, under a royalty-sharing or other policy in which license proceeds are distributed to inventors.

Supplemental CCI Policy

Given the breadth of the Harvard Policy, there will not arise for the CCI any situations in which a faculty investigator seeks permission to conduct a clinical trial sponsored by a company in which the investigator holds an equity interest. If they do, the application should be denied, on referral to the Vice President for Research or the Office of General Counsel, as a violation of Harvard Medical School faculty policy.

However, it is important to state (a) how such conflicts will be addressed for non-faculty investigators; (b) how other investigator conflicts will be addressed; and (c) how conflicts arising from institutional equity will be addressed. These points are addressed as follows:

(a) The CCI agrees with the Harvard Policy prohibition on faculty investigators conducting clinical research sponsored by companies in which they hold equity interests, and will apply that prohibition to non-faculty investigators as well.

(b) Other investigator conflicts of interest that are not addressed by the Harvard Policy will be addressed under the CCI "Policy for Clinical Research Conflict of Interest".

(c) The CCI will not approve clinical trials of a test article sponsored by a licensee in which the Hospital holds license-related equity except in extraordinary situations, as demonstrated by the presence of *all* of the following circumstances: (1) there is no other appropriate venue for the study of a diagnostic or therapy of significant potential benefit to the public or to Hospital patients; *and* (2) there is independent verification and monitoring of all significant aspects of the study relevant to human subject protection and scientific integrity, including protocol design, description of risks and benefits, implementation of exclusion and inclusion criteria, securing informed consent, criteria and procedures for subject withdrawal, reporting and addressing adverse events, maintaining research subjects' awareness of their rights, and reporting of data; *and* (3) any additional conditions the CCI has imposed, in its sole discretion, under the "Policy for Clinical Research Conflict of Interest" are or will be satisfied. The Hospital's equity and any other financial interests must also have been fully disclosed to any other involved institutional review board. Those interests must be further disclosed, in a manner approved by the CCI, to all patients who are solicited to become research subjects.

Under no circumstances may any clinical trial be overseen solely by an inventor of a test article that is the subject of the trial. Except in extraordinary circumstances in which the inventor's involvement is necessary to assure the safety of subjects because of the inventor's unique knowledge of a device or other test article, an inventor should not be the principal investigator in the clinical trial concerning that test article, nor should the principal investigator be directly or indirectly supervised by an inventor.

Related Content

Document Attributes

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