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## **Responsibilities of Investigators**

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**The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true.**

**--Albert Einstein (inscribed on the base of the Albert Einstein memorial at the National Academy of Sciences)**

The success of the scientific enterprise requires first of all that scientists must embody honesty and integrity in every phase of their work. Without the uncompromising integrity of everyone involved in research, the entire edifice of science will eventually collapse, because each new layer of knowledge is built on the accuracy and truth of the research that preceded it.

A great deal has been written in recent years on research integrity, fueled by such highly publicized cases as those involving Thereza Imanishi Kari and David Baltimore in Boston<sup>1</sup>, Robert Gallo at the NIH<sup>2</sup>, and Francis Collins at the Human Genome Project,<sup>3</sup> each accused of transgressions against the ethical and legal norms that guide research. Integrity in science means that the investigators accept responsibility for all aspects of a study, from experimental design through all stages of its execution, including publication. It implies that each of these steps will be carried out with competence and honesty.

Integrity in research cannot be assured by law; it must come from the character of those who carry out research. Nevertheless, medical journals have an important role to play in reminding those who do research of their obligations to science. For example, conflicts of interest arising from financial or other kinds of ties to companies whose products are being studied may be a source of bias in reporting research results. Journals have taken several different approaches to dealing with these kinds of conflicts. Taking a firm position, the New England Journal of Medicine in 1990 announced a policy in which they would refuse to publish any article or editorial written by an employee of a company (or its competition) whose product is important to

the topic under discussion.<sup>4</sup> Many protested that this policy was overly zealous, akin to throwing out the baby with the bath water. For example, under a policy of this kind, it has been pointed out, Thomas Edison could not have published an article on the future of electricity.<sup>5</sup>

The *Annals of Thoracic Surgery* and the *Journal of Thoracic and Cardiovascular Surgery* deal with such conflicts of interest by requiring that authors report any potential conflict at the time of submission of their manuscripts. The editors may then publish such conflicts with the article, allowing readers to make their own judgments about potential bias and possible effects on interpreting the research results. Even a reasonable policy such as this still may be problematic. For example, the term ‘conflict of interest’ has pejorative connotations, so even relatively minor conflicts may result in reports being judged *ad hominem*, on the basis of personal characteristics of their authors rather than strictly on their merits.<sup>5</sup>

Yet another issue may directly affect integrity in the reporting of research: control of research data and of decisions to publish or not to publish by entities other than the investigator; for example, industrial sponsors or institutions such as universities. Industry now provides substantial support for research that often results in very good science with important clinical implications. Yet, there have been several instances in recent years when publication of research results was delayed or entirely blocked by companies that had financially supported studies that produced results unfavorable to their products.<sup>6,7</sup> Although we know of no published examples of such problems in cardiothoracic surgery, the large volume of industry-sponsored research in our field suggests that it almost certainly exists. A recent survey of academic life scientists found that nearly 20 percent of them admitted that publication of their research results had been significantly delayed (six months or longer) for a variety of reasons, including disputes over ownership of intellectual property.<sup>8</sup> Universities may demand similar delays in publication

because of intellectual property issues. In one notorious recent case, a university supported an industrial sponsor's blockage of publication by one of its faculty members. A clinical study produced unexpected negative results for the company's product, and when the physician-researcher pursued publication anyway, the company's attempt to stop it (which eventually failed) was supported by the university against their own faculty member. A series of lawsuits resulted.<sup>9</sup>

In view of the disturbing trend of interference with publication of research results, the International Committee of Medical Journal Editors (ICMJE) has revised the "Uniform Requirements For Manuscripts Submitted To Biomedical Journals: Writing and Editing for Biomedical Publication."<sup>10</sup> The new guideline is clear about the accountability of scientists for their own research: "As the persons directly responsible for their work, researchers therefore should not enter into agreements that interfere with their access to the data or their ability to analyze the data independently, to prepare manuscripts, and to publish them". The issue of responsibilities of investigators *vis a vis* sponsoring companies was recently considered at some length in an editorial that was published simultaneously in 12 medical journals in the fall of 2001.<sup>10</sup> In their editorial, the group of editors concluded that, because a manuscript is the intellectual property of the research scientists rather than the sponsors of the study, "we will not review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication."

The editors of the *Annals* and the *Journal* have expressed support for the general thrust of the multi-authored editorial. They also support a specific policy to consider rejecting a manuscript describing a study in which an entity other than the investigator either had sole control of the data or had veto power over publication. Both the *Annals* and the *Journal* have added new

language to their respective "Information For Authors" pages that reflects this policy change. The added language states: "Each author must indicate whether or not he or she has had full 'Freedom of Investigation' before, during and after this study. 'Freedom of Investigation' is defined as freedom from outside interests controlling the design of the study, acquisition of data, collection, analysis, and interpretation of data, or having veto power over full disclosure of the results." If the investigators did not have full freedom of investigation, a letter of explanation will be required, and publication may be denied.

Collaboration between industry and research scientists has been abundantly fruitful, and university administrations have put in place systems that accommodate industry sponsored research. These have made possible great advances in the care of thoracic surgical patients. Yet, there have been occasions when these usually nurturing hands have challenged the integrity of science. The journal policy we describe is intended to have two effects. One is to give investigators powerful support from our specialty's most prestigious and largest circulation journals in negotiating ethically acceptable contracts with industrial sponsors and in dealing with undue delays imposed by others, such as intellectual property officers of universities. The second is to assure that readers of our journals have enough information to make informed judgments about potential biases in research results and their interpretation, with the understanding that the authors had control of the data and its analysis and of the decision to publish. The accuracy of the information provided to the editors rests upon the long tradition of expecting that the information requested of authors will be provided fully and honestly. Journals must be able to rely on the integrity and honesty of investigators in providing accurate information to their readers, for these character traits are the life blood of the entire corpus of cardiothoracic research and the clinical practices that depend upon it.

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